VOLAR DISTAL RADIUS FRACTURE SOLUTIONS

Value Analysis Committee Resource Guide
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>About Flower Orthopedics</td>
<td>1</td>
</tr>
<tr>
<td>The FlowerCube™</td>
<td>2</td>
</tr>
<tr>
<td>Flower Locking Mechanism</td>
<td>4</td>
</tr>
<tr>
<td>FlowerBasic™ and FlowerAnatomic™</td>
<td>5</td>
</tr>
<tr>
<td>Distal Radius Fracture Solutions</td>
<td>6</td>
</tr>
<tr>
<td>510 (k) Clearance Letters</td>
<td>7</td>
</tr>
</tbody>
</table>
About Flower Orthopedics

At Flower Orthopedics, we are creating new Standards for Orthopedics by providing cost-effective, safe and efficient, Ready-for-Surgery™ treatment concepts.

Our transformative bone-fixation solutions consist of sterile-packaged implants that feature our patented Flower Locking System. Each implant is matched with our revolutionary, single-use, disposable Flower Instrument Kit.

The Flower Ready-for-Surgery Cube provides complete and standardized surgical Applications that eliminate the need for pre-op handling and post-op reprocessing. Flower Orthopedics’ real-world innovations are redefining the protocols and standards for Orthopedics.

At Flower, we focus on cost savings while ensuring clinical excellence.

Mr. Oliver Burckhardt and Zrinski AG, Germany founded Flower Orthopedics Corporation (Flower) in June of 2012. The company was established on the technology of the Zrinski Locking Mechanism, invented by Zrinski AG in 2009.

Today, Flower offers eight different FlowerApplications™. Every FlowerApplication has implants and instruments needed to cover a range of surgical indications in a specific anatomical location. All applications are focused on inventory and surgical case efficiency to ensure cost savings.

Over the last two years Flower has developed approximately 1,000 implantable products, and has created never before seen disposable instruments that compare in high-quality and function to reusable instruments commonly used in the market place. Today, Flower’s surgical solutions have been clinically validated by physicians, ambulatory and acute care facilities. The FlowerCube and the FlowerApplications are considered the next logical pathway into a new era of surgical implants and disposable application tools.

Flower Orthopedics is located in Horsham, Pennsylvania, with a nationwide distribution network.

“Our Mission is to eliminate Operating Room Uncertainty and Drive Efficiencies to ensure predictable patient outcomes while Reducing Overall Case Expenditure.”
The FlowerCube™ – The New Standard in Bone Fixation

The FlowerCube is at the heart of everything we do at Flower Orthopedics. Tailored for specific surgical indications, the FlowerCube houses all of the requisite implants and instruments sterile packaged, disposable and always Ready-for-Surgery™. The FlowerCube is delivered ready for use, eliminating preoperative, on-site sterilization.

Within Each FlowerCube you will find the following:

**FlowerCarriage™** - The FlowerCarriage contains implants, instruments, and appliances required for a specific bone-fixation surgery. It is made from a sturdy and unique material that allows the surgical team to carry the Carriage, organized with all essential application-specific implants and instruments, in and out of the surgical suite.

**Flower Implants** - Providing the ultimate in secure bone-fixation, each sterile-packaged, titanium Flower Implant is designed for a particular indication. Every implant is visible in its package, and the packages are clearly marked and color coded for simplified handling and easy recognition. QRC codes and bar codes allow for lot tractability.

**Flower Trials** - Sterile-packaged Flower Trials are included in each cube. The Trials are used to pinpoint the exact implant size prior to opening the correct implant box. The laser-marked number on the removed section of each Trial indicates the correct implant size.

**Flower Instrument Kits** - All implant-based instruments needed for the procedure are included in the Instrument Kit. The Ready-for-Surgery instruments provide the added assurance that the right surgery-specific tools are in place and in prime condition. Each instrument is sterile, robust, and disposable. There is no need for post-op decontamination.
**Flow**erCube™: Schedule. Treat. Turn.

**Schedule Case Faster.**
(Ready-for-Surgery™)
- No cleaning and sterilization
- FlowerCube is always ready to complete the case
- No time consuming set drop off

**Treat Patient Safer.**
(Sterile & Disposable)
- Instrument kits always complete
- Drill bits always sharp
- Guaranteed sterility

**Turn OR Quicker.**
(FlowerCube)
- FlowerCube always ready for the next surgery
- No delay with back to back cases
- Enough sterile inventory for multiple cases

---

**Flow**erCube — Redefining Infection Prevention

Flow**erCubes are pre-packaged and ready for use, eliminating costly pre-op sterilization. The instruments are robust, disposable, and new every time, eliminating the traditional wear and tear of instrumentation and post-op decontamination.

The FlowerCube maximizes efficiencies by streamlining and simplifying the ordering process while minimizing inventory levels and costs.
Flow er Locking Mechanism

Our patented locking principle is based on a titanium-alloy, polyaxial screw with a bone and locking thread, which is inserted and locked into the FlowerGroove™ of the plate (titanium). By applying a defined torque, the screw head is compressed into the FlowerGroove, which then creates interference that locks the screw head into the FlowerGroove. The locked angle stability secures the screw in the plate and avoids any potential for backwards migration of the screw.

Flower Orthopedics has developed over 400 plates that can be used for various indications. All of the Flower implants are manufactured to the highest quality and standards, and all use two standardized locking diameter ranges (Flower Small, Flower Medium).

For indications where a Locking Screw is not desired, Flower developed variable angle non-locking screws that can be placed in the Flower Locking hole, without engaging the locking mechanism.

Secure Locking at any angle:

- Variable Angle Screws can be inserted up to ±15° in all directions
- Variable Angle Locking Screws are securely locked through the range of insertion angles
- FlowerGroove eliminates potential cross-threading
- Locking engagement begins at final screw turn
- Titanium: Screw, Grade 5; Plate, Grade 2 → produces a robust locking construct
- Permanent, yet reversible locking → Surgeon can position locking screw up to 3 times (if necessary)
- Torque Limiting Screw Driver provides audible & tactile assurance that construct is locked
- FlowerGroove also accepts Variable Angle Non-Locking Screws
Flowe rB asic™ and Flowe rA natom ic™

Flowe r Orthopedics carries two distinct product lines; Flowe rB asic and Flowe rA natom ic. Plates in both product lines are made out of grade 2 titanium in Germany, adhering to the strictest manufacturing guidelines. Flowe rB asic plates are for general, and multi-use and include our extensive line of Recon and Osteosynthesis plates. Flowe rA natom ic plates are all anatomically contoured, low profile and engineered for specific applications.

Both Flowe rB asic and Flowe rA natom ic use our standard instrumentation, and are available in pre-built and customized Flowe rCubes™.

<table>
<thead>
<tr>
<th>FlowerB asic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distal Radius Plates, Volar</td>
</tr>
<tr>
<td>Recon Plates (Small, Medium)</td>
</tr>
<tr>
<td>Osteosynthesis Plates (Small, Medium)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Flowe rA natom ic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anatomic Distal Radius Plates, Volar</td>
</tr>
<tr>
<td>Proximal Humerus Plates</td>
</tr>
<tr>
<td>Hand Plates (Small)</td>
</tr>
<tr>
<td>Foot Plates (Small, Medium)</td>
</tr>
<tr>
<td>Ankle Plates</td>
</tr>
</tbody>
</table>

Flowe rB asic: Distal Radius Plates, Volar

The Flowe rB asic product lines carries Small (2.0mm thickness) and Medium (2.4mm thickness) Volar Distal Radius Plates. Plates are available in Narrow and Wide, and Left/Right Configurations

- Economical, yet robust plates and instruments
- Targeted screw holes provide enhanced fixation
- K-Wire holes provide fracture reduction and aid in the correct plate placement
- Plate window allows direct visualization, bone graft application and fragment manipulation through the plate
- Plate trial templates simplify plate selection and act as bending template
- Streamlined instrumentation provides ease of use with zero learning curve
Anatomic fracture reduction and stabilization can be achieved with the precontoured distal radius plates. Developed through comprehensive morphology analysis, the plates rarely require bending to match the complex geometry of the distal radius. The plate design expedites intraoperative restoration of the patient’s anatomy, optimum plate placement and construct stabilization.

The anatomic contour provides optimized intermediate and radial column support, while fragments are structurally buttressed to the anatomy. Appropriately spaced distal screw holes deliver optimal subchondral support and fragment reduction.

Plates, designed to minimize soft tissue disruption, naturally sit proximal to the watershed line.

Targeted locking screw holes provide enhanced fixation, precise to anatomic fragments of the radial styloid and volar ulnar corner.

The preassembled, radiolucent guide block facilitates easy plate insertion and preliminary plate fixation with K-wires. The patent-pending design promotes proper plate and screw placement while reducing the number of steps, and potentially amount of fluoroscopy, needed for implantation.

A K-wire hole targeted to the tip of the radial styloid provides access to reduce small and large fragments.

Plate window allows direct visualization, bone graft application and fragment manipulation through the plate.

Plates are manufactured from Grade 2 commercially pure titanium providing an elastic modulus closer to that of bone than titanium alloy or stainless steel and reducing the propensity of stress shielding according to Wolff’s law.

All screw holes accept both locking and non-locking screws.

Plate trial templates simplify plate selection and act as bending template, for extreme anatomy.

Streamlined instrumentation provides ease of use with zero learning curve.
510(k) SUMMARY

Flower Orthopedics Corporation’s Flower Small and Medium Implants

Submitter’s Name, Address, Telephone Number, Contact Person, and Date Prepared

Flower Orthopedics Corporation
7715 Crittenden Street, #413
Philadelphia, PA 19118

Phone: +1 267 437 3063
Facsimile: +1 267 437 3072

Contact Person: Oliver B. Burckhardt

Date Prepared: March 29, 2013

Name of Device and Name/Address of Sponsor

Flower Small and Medium Implants

Common or Usual Name

Bone plating system

Classification Name/ Product Code

Classification Name: 21 CFR 888.3030 – Single/multiple component metallic bone fixation appliance and accessories

Product Codes: HRS (Plate, Fixation, Bone), HWC (Screw, Fixation, Bone)

Predicate Devices

Synthes USA’s 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications (K082807)
Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad Locking Compression Plates (LCP) (K092609)
Stryker’s VariAx Distal Radius Locked Plating System Line Extension for Addition of Aiming Blocks (K112455)
KLS-Martin Hand Plating System (K040598)
Synthes 2.4mm VA-LCP Intercarpal Fusion System (K103243)
Intended Use / Indications for Use

The Flower Small and Medium Implants set is intended for use for internal fixation of fractures and reconstruction of bones, including the scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, hand and foot in adults and for use in long bones in adolescents (12-21) in whom the growth plates have fused. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra-articular fractures, displaced fractures, osteotomies, non-unions and mal-unions.

This system can be used for palmar, ventral, dorsal or orthogonal application.

Technological Characteristics

The Flower Small and Medium Implants set consists of the following components and accessories: pure titanium small straight plates, small and medium reconstruction plates, medium osteosynthesis plates, proximal humerus plates, distal radius plates, L-shaped plates, T-plates, angular T-shaped plates, H-shaped plates, mediocarpal plate; and titanium alloy screws. The device is also provided with general purpose instruments. All plates are made of pure titanium (ISO 5832-2).

The Flower Small and Medium Implants set provides fixed-angle lockable screws and plates to assist with internal fixation of fractures and reconstruction of bones. The principles of operation of the device are similar to other bone plating systems. The plates are comprised of various shapes, alignments, thicknesses, widths, and lengths designed to contour to different bones and locations on the body for internal fixation or reconstruction following fracture. Each of the plates contains several locking holes that allow for the insertion of Flower Small and Medium Implants locking screws. To use the Flower Small and Medium Implants set, the surgeon first selects an implant of the appropriate size and shape based on the intended site of use. The plate should be placed in an appropriate location on the given bone or anatomical location in need of repair.

Performance Data

In support of this 510(k) Premarket Notification, Flower Orthopedics has conducted the following testing. In all instances, the Flower Small and Medium Implants set functioned as intended.

- Biocompatibility in accordance with ISO 10993-1, ISO 10993-5 was established, demonstrating that the materials are non-cytotoxic and biocompatible.
- Sterilization validation of implants and instruments demonstrated assurance level of $10^{-6}$ for this method of sterilization using the specified gamma sterilization cycle.
- Packaging validation and shelf life testing ensured that the packaging can maintain its physical integrity and maintain a sterile barrier over the stated period.

Substantial Equivalence

The Flower Small and Medium Implants system is very similar to Synthes’s 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications (K082807), the Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad Locking Compression Plates (LCP) (K092609), Stryker’s Varix Distal Radius Locked Plating System Line Extension for Addition of Aiming Blocks (K112455), KLS-Martin’s Hand Plating System (K040598), and Synthes 2.4mm VA-LCP Intercarpal Fusion System (K103243). The Flower Small and Medium Implants system has the same intended
uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The overall surgical procedure for the Flower Small and Medium Implants set and the predicate devices are very similar and there are no new types of safety or effectiveness concerns. The minor difference in the locking feature between the Flower system and the predicate systems do not significantly alter the surgical technique. The minor technological differences between the Flower Small and Medium Implants and its predicate devices, e.g., minor differences in the range of available geometries and dimensions, raise no new types of safety or effectiveness questions because these size differences are very minor and are largely encompassed within the range of similar parameters in the predicate devices. Engineering analysis has been performed to demonstrate that the Flower Small and Medium Implants system provides appropriate mechanical strength for its intended use. Thus, the Flower Small and Medium Implants system is substantially equivalent.
Flower Orthopedics Corporation 
% Hogan Lovells US LLP 
Ms. Janice M. Hogan, Partner 
1835 Market Street, 29th Floor 
Philadelphia, Pennsylvania 19103

Re: K123562 
Trade/Device Name: Flower Small and Medium Implants 
Regulation Number: 21 CFR 888.3030 
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories 
Regulatory Class: Class II 
Product Code: HRS, HWC 
Dated: March 1, 2013 
Received: March 1, 2013

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set
forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use Statement

510(k) Number (if known): K123562

Device Name: Flower Small and Medium Implants

Indications for Use:

The Flower Small and Medium Implants set is intended for use for internal fixation of fractures and reconstruction of bones, including the scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, hand and foot in adults and for use in long bones in adolescents (12-21) in whom the growth plates have fused. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extraarticular fractures, displaced fractures, osteotomies, non-unions and mal-unions.

This system can be used for palmar, ventral, dorsal or orthogonal application.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Krishna R. Asundi
2013.03.29 15:27:49 -04'00'

Page _ of ___
5. 510(k) SUMMARY

<table>
<thead>
<tr>
<th>Submitter’s Name:</th>
<th>Flower Orthopedics Corporation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitter’s Address:</td>
<td>7715 Crittenden Street, #413 Philadelphia, PA 19118</td>
</tr>
<tr>
<td>Submitter’s Telephone:</td>
<td>267-437-3063</td>
</tr>
<tr>
<td>Submitter’s Fax:</td>
<td>267-437-3072</td>
</tr>
<tr>
<td>Authorized Contact Name:</td>
<td>Janice M. Hogan</td>
</tr>
<tr>
<td>Contact’s Telephone:</td>
<td>267-675-4611</td>
</tr>
<tr>
<td>Contact’s Email:</td>
<td><a href="mailto:janice.hogan@hoganlovells.com">janice.hogan@hoganlovells.com</a></td>
</tr>
<tr>
<td>Date Summary was Prepared:</td>
<td>July 26, 2013</td>
</tr>
<tr>
<td>Trade or Proprietary Name:</td>
<td>Flower Small and Medium Implant Set</td>
</tr>
<tr>
<td>Common or Usual Name:</td>
<td>Bone plating system</td>
</tr>
<tr>
<td>Classification:</td>
<td>Class II per 21 CFR §888.3030</td>
</tr>
<tr>
<td>Product Codes:</td>
<td>HRS, HWC</td>
</tr>
<tr>
<td>Classification Panel:</td>
<td>Orthopedic and Rehabilitation Devices Panel</td>
</tr>
<tr>
<td>Predicate Devices:</td>
<td>Flower Small and Medium Implant Set (K123562) Synthes USA’s 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications (K082807) Stryker’s VariAx Distal Radius Locked Plating System Line Extension for Addition of Aiming Blocks (K112455) KLS-Martin Hand Plating System (K040598)</td>
</tr>
</tbody>
</table>

CHANGE FROM PREDICATE:
The purpose of this submission is to make modifications (line extensions) to the components of the Flower Small and Medium Implant Set cleared in K123562. The standard construct is modified by adding sizes not included in the previous submission.

TECHNOLOGICAL CHARACTERISTICS:
The Flower Small and Medium Implants set consists of the following components and accessories: pure titanium small straight plates, small and medium reconstruction plates, medium osteosynthesis plates, proximal humerus plates, distal radius plates, L-shaped plates, T-plates, angular T-shaped plates, H-shaped plates, mediocarpal plate; and titanium alloy screws. The device is also provided with general purpose instruments.
INDICATIONS FOR USE
The Flower Small and Medium Implants set is intended for use for internal fixation of fractures and reconstruction of bones, including the scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, hand and foot in adults and for long bone in adolescents (12-21) in whom the growth plates have fused. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra-articular fractures, displaced fractures, osteotomies, non-unions and mal-unions.

This system can be used for palmar, ventral, dorsal or orthogonal application.

PERFORMANCE DATA
In support of this 510(k) Premarket Notification, Flower Orthopedics has conducted engineering analysis to demonstrate that the modifications to the Flower Small and Medium Implants set provides adequate and substantially equivalent mechanical strength for its intended use.

CONCLUSION
The Flower Small and Medium Implants system is very similar to previously cleared Flower Small and Medium Implant Set. The Flower Small and Medium Implants system has the same intended uses and similar indications, technological characteristics, and principles of operation as the previously cleared devices. The minor technological differences between the subject Flower Small and Medium Implants and its previously cleared devices raise no new types of safety or effectiveness questions. The overall technology characteristics lead to the conclusion that Flower Small and Medium Implant Set is substantially equivalent to the previously cleared devices.
Flower Orthopedics Corporation
% Ms. Janice M. Hogan
Partner
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

August 22, 2013

Re: K131657
   Trade/Device Name: Flower Small and Medium Implant Set
   Regulation Number: 21 CFR 888.3030
   Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
   Regulatory Class: Class II
   Product Code: HRS, HWC
   Dated: July 26, 2013
   Received: July 26, 2013

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21
CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
4. **INDICATIONS FOR USE STATEMENT**

Device Name: Flower Small and Medium Implant Set

The Flower Small and Medium Implants set is intended for use for internal fixation of fractures and reconstruction of bones, including the scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, hand and foot in adults and for long bone in adolescents (12-21) in whom the growth plates have fused. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra-articular fractures, displaced fractures, osteotomies, non-unions and mal-unions.

This system can be used for palmar, ventral, dorsal or orthogonal application.

Prescription Use __X___ AND/OR Over-The-Counter Use ________

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S
Division of Orthopedic Devices
510(k) SUMMARY

Flower Bone Screw Set

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Flower Orthopedics Corporation
7715 Crittenden Street, #413
Philadelphia, PA 19118

Phone: (267) 437 3063
Facsimile: (267) 437 3072

Contact Person: Oliver Burckhardt, Chief Executive Officer
Date Prepared: October 29, 2013

Name of Device and Name/Address of Sponsor

Flower Bone Screw Set

Common or Usual Name/Classification Name

Bone Fixation Screw

Product Codes: HWC; HTN (Orthopedic Review Panel)

Product Classifications: 21 C.F.R. 888.3040 - Smooth or Threaded Metallic Bone Fixation Fastner; 21 C.F.R. 888.3030 - Single/multiple component metallic bone fixation appliances and accessories

Predicate Devices

Medical Facets Bone Fixation Screws and Pins (K12727)
Howmedica Asnis Micro Cannulated Screw (K071092)
Treu Bone Fixation Screws and Pins (K083912)
Synthes 4.5mm and 6.5mm Headless Compression Screws (K080943)
Flower Small and Medium Implant Set (K123562)

Intended Use / Indications for Use

The Flower Bone Screw set is intended to be used for the fixation of bone fractures, fusion of joints or bone reconstruction.

Device Description

The Flower Bone Screw Set consists of the following components and accessories: solid, cannulated, and headless compression screws, as well as washers, all made of a titanium alloy compliant with ASTM F136. The device is provided with general purpose instruments.

Technological Characteristics

The Flower Bone Screw Set consists of the following components/configurations:
• Cannulated Bone Screws with a diameter range of 2.0-7.3mm and a length range of 10.0-130.0mm;
• Solid Bone Screws with a diameter range of 2.0-4.5mm and a length range of 10.0-70.0mm; and
• Headless Compression Bone Screws with a 6.5mm diameter and a length range of 45.0-130.0mm.

Performance Data

The Flower Bone Screw Set was tested (worse case) according to the following standards:

- ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401);
- ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process;
- ISO 10993-5, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity;
- ISO 11137-1, Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. (Sterility)

In addition, an engineering analysis has been performed to demonstrate that the Flower Orthopedics cannulated, solid and headless compression bone screws provide appropriate mechanical strength for the claimed intended use.

In all instances, the Flower Bone Screw Set functioned as intended and test results, as well as an engineering analysis, demonstrate substantial equivalence with the cited predicate devices.

Substantial Equivalence

The Flower Bone Screw Set is substantially equivalent to the identified predicate devices. The subject devices have the same intended uses /indications, technological characteristics, and principles of operation as its predicate devices. An engineering analysis was performed to demonstrate that the Flower Orthopedics cannulated, solid and headless compression bone screws provide appropriate mechanical strength for the claimed intended use. Thus, the subject bone screws are substantially equivalent.
October 30, 2013

Flower Orthopedics Corporation
% Ms. Janice M. Hogan
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K132248
Trade/Device Name: Flower Bone Screw Set
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: September 18, 2013
Received: September 18, 2013

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set
forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic
product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please
contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-
free number (800) 638-2041 or (301) 796-7100 or at its internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note
the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part
807.97). For questions regarding the reporting of adverse events under the MDR regulation (21
CFR Part 803), please go to
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH’s Office
of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the
Division of Small Manufacturers, International and Consumer Assistance at its toll-free number
(800) 638-2041 or (301) 796-7100 or at its Internet address

Sincerely yours,

Erin Keith

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use Statement

510(k) Number (if known): K132248

Device Name:

Indications for Use:

The Flower Bone Screw Set is intended to be used for the fixation of bone fractures, fusion of joints or bone reconstruction.

Prescription Use __ X __ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth Frank -S
Division of Orthopedic Devices
November 18, 2013

Flower Orthopedics Corporation
% Ms. Janice M. Hogan
Regulatory Counsel
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K133102
Trade/Device Name: Flower Ankle Plating Set
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: September 30, 2013
Received: September 30, 2013

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21
CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbraniding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use Statement

510(k) Number (if known): K133102

Device Name: Flower Ankle Plating Set

Indications for Use:

The Flower Ankle Plating Set is intended for use for fixation of the ankle in adults and adolescents (12-21) in whom the growth plates have fused, and particularly in osteopenic bone. Specifically,

- Distal Medial and Lateral Tibia Plates are intended for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia,
- Distal Tibia A-Plates are intended to buttress partial articular fractures and bone fragments of the distal tibia, and
- Straight and Distal Lateral Fibula Plates are intended for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal fibula.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line-continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank - S
Division of Orthopedic Devices
Dear Mr. Barnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set
forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act; 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use Statement

510(k) Number (if known): K133930

Device Name: Flower Rearfoot Plating Set

Indications for Use:

The Flower Rearfoot Plating Set is intended to be used for internal fixation of fractures and reconstruction of bones of the rearfoot, including the calcaneus. Examples of these internal fixations and reconstructions include, but are not limited to extra-articular fractures, intra-articular fractures, joint depression fractures, tongue type fractures, severely comminuted fractures and osteotomies.

Prescription Use

X

(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use

(21 CFR 801 Subpart C)

( PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth

Division of Orthopedic Devices

Frank -S