DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 6, 2017

Flower Orthopedics Corporation
Ms. Jessica Huang
Manager, Regulatory Affairs and Quality Assurance
100 Witmer Road, Suite 280
Horsham, Pennsylvania 19044

Re: K170687
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
Dated: May 5, 2017
Received: May 8, 2017

Dear Ms. Jessica Huang:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,
Vincent J. Devlin -S
for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170687

Device Name

Flower Bone Screw Set

Indications for Use *(Describe)*

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Special 510(k) SUMMARY

Flower Bone Screw Set

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

Flower Orthopedics Corporation
100 Witmer Road, Suite 280
Horsham, PA 19044

Phone: (215) 323-4018
Facsimile: (215) 394-8904

Contact Person: Jessica Huang, Manager, Quality Assurance and Regulatory Affairs
Date Prepared: June 6, 2017

Name of Device and Name/Address of Sponsor

Flower Bone Screw Set
Flower Orthopedics Corporation
100 Witmer Rd. Suite 280
Horsham, PA 19044

Common or Usual Name/Classification Name

Bone Fixation Screw (Product Code: HWC); Product classification: 21 C.F.R. 888.3040 – Smooth or threaded metallic bone fixation fastener

Predicate Devices

Flower Bone Screw Set (K132248)
Flower Small and Medium Implant Set (K123562)
Medical Facet's Bone Fixation Screws and Pins (K112727)

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 subject Flower Bone Screw Set is an extension of the Flower Bone Screw Set (K132248) consisting of headless compression screws and cannulated bone screws, made of a titanium alloy compliant with ISO 5832-3. The device is provided with general purpose instruments.

Changes from Predicate

The purpose of this submission is to add components to the Flower Bone Screw Set cleared in K132248. The standard construct is modified by adding sizes for Headless Compression Screw and Cannulated Screws not included in the previous submission.

Technological Characteristics

The following components/configurations are being added to the Flower Bone Screw Set:

- Cannulated Bone Screws with a diameters of 2.0mm and 2.4mm with additional lengths of 6mm and 8mm with total lengths ranging from 6mm to 50mm;
- Cannulated Screws of 3.0mm diameter with minor change to thread lengths;
- Headless Compression Bone Screws with 2.2mm, 2.4mm, 3.0mm, 3.5mm, 4.0mm diameters and a length range of 6.0-60.0mm.

Performance Data

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

- ASTM/AAMI ST72, Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing

In addition, an engineering analysis has been performed to demonstrate that the Flower Orthopedics bone screws provide adequate and substantially equivalent mechanical strength for the claimed intended use.

Conclusion

The Flower Bone Screw set is very similar to the previously cleared Flower Bone Screw Set. The subject devices have the same intended uses and indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the subject devices and the predicate devices raise no new issues of safety or effectiveness. An engineering analysis was performed to demonstrate that the Flower Orthopedics bone screw set provides appropriate mechanical strength for the claimed intended use. Thus, the subject bone screw set is substantially equivalent to the predicate devices.