DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 15, 2014

Flower Orthopedics Corporation
Mr. Gary Barnett
RA/RQ Manager
100 Witmer Road, Suite 280
Horsham, Pennsylvania 19044

Re: K142306
Trade/Device Name: Flower Upper Extremity Plating Set
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: August 15, 2014
Received: August 19, 2014

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 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" (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 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 yours,

Lori A. Wiggins -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): K142306

Device Name: Flower Upper Extremity Plating Set

Indications for Use:

The **Flower Upper Extremity Plating Set** is intended to be used for fixation of fractures, fusions, or osteotomies of the clavicle, humerus, radius and ulna.

Prescription Use ___**X**____ (Part 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)

510(k) SUMMARY

Flower Orthopedics Corporation's
Upper Extremity Plating 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) 394-8903
Facsimile: (215) 394-8904

Contact Person: Gary Barnett
Date Prepared: August 15, 2014

Name of Device

Flower Upper Extremity Plating Set

Common or Usual Name/Classification Name

The Flower Upper Extremity Plating Set consists of bone plates classified under product code HRS (21 C.F.R. 888.3030, Single/multiple component metallic bone fixation appliance and accessories; Class II) and bone fixation screws classified under product code HWC (21 C.F.R. 888.3040, Smooth or threaded metallic bone fixation fastener; Class II).

Predicate Devices

Acumed Inc., Congruent Bone Plating System (K012655, K063640, K071715)
Flower Orthopedics, Small and Medium Implant Set (K123562, K131657)

Intended Use / Indications for Use

The Flower Upper Extremity Plating Set is intended to be used for fixation of fractures, fusions, or osteotomies of the clavicle, humerus, radius and ulna.

Device Description

The Flower Upper Extremity Plating Set consists of the following components and accessories: midshaft clavicle plates, distal clavicle plates, medial distal humerus plates, lateral distal humeral plates, posterior lateral distal humerus plates, olecranon plates, coronoid plates, variable angle locking screws, variable angle non-locking screws. The plates are all made of pure titanium compliant with ASTM F67, the screws are made of titanium alloy compliant with ASTM F136. The system accepts locking and non-locking screws cleared via K123562 and K131657, the locking and non-locking screws included in this submission extend the length range of the previously cleared screws. The device is provided with general purpose instruments, including appropriately sized trials.

Technological Characteristics

The Flower Upper Extremity Plating Set consists of the following components/configurations:
Midshaft Clavicle Plates, with a width of 11 mm and lengths of 70/110 mm;
Distal Clavicle Plates, with a width of 11 mm and lengths of 91/136 mm;

Medial Distal Humerus Plates, with a width of 11 mm and lengths of 78/140 mm;
Lateral Distal Humerus Plates, with a width of 11 mm and lengths of 87/146 mm;
Posterior Lateral Distal Humerus Plates, with a width of 11 mm and lengths of 100/148 mm;
Olecranon Plates, with a width of 10 mm and lengths of 95/135 mm;
Coronoid Plates, with a width of 21 mm, and 40mm lengths;
Variable Angle Locking Screws: 2.7 mm, 3.0 mm, 3.5 mm, 4.0 mm dia. x 65 mm long;
Variable Angle Non-Locking Screws: 2.7 mm, 3.0 mm, 3.5 mm dia. X 8 mm long;
Variable Angle Non-Locking Screws: 2.7 mm, 3.0 mm dia. X 60 mm long
Variable Angle Non-Locking Screws: 2.7 mm, 3.0 mm, 3.5 mm, 4.0 mm dia. X 65 mm long

Performance Data

The Flower Upper Extremity Plating Set was tested (worse case) according to the following standards:

- ASTM F67, Standard Specification for Unalloyed Titanium for Surgical Implant Applications
- ISO 5832-2, Implants for Surgery, Metallic Materials. Part 2: Unalloyed Titanium
- ASTM F136, Standard Specification for Wrought Titanium- 6 Aluminum- 4 Vanadium ELI Alloy for Surgical Implant Applications
- ISO 5832-3, Implants for Surgery. Metallic materials. Part 3: Wrought titanium 6-aluminium 4-vanadium alloy;
- ISO 7153-1, Surgical instruments – Metallic materials – Part 1: Stainless steel (ISO 7153-1:1991, including Amendment 1:1999); German version EN ISO 7153-1:2000;
- 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 was performed to demonstrate that the subject upper extremity plates provide appropriate mechanical strength for the claimed intended use.

In all instances, the Flower Upper Extremity Plating 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 Upper Extremity Plating 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 the predicate devices. An engineering analysis was performed to demonstrate that the components in the Flower Upper Extremity Plating Set provide appropriate mechanical strength for the claimed intended use. Thus, the subject upper extremity plates are substantially equivalent and do not present any new risks.