NOV 1 8 2013



K133102

**510(k) SUMMARY**

**Flower Orthopedics Corporation's**
**Ankle Plating 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: September 30, 2013

**Name of Device**

Flower Ankle Plating Set

**Common or Usual Name/Classification Name**

The Flower Ankle Plating Set consists of bone ankle 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**

Synthes USA, Synthes 2.7mm/3.5mm LCP Distal Fibula Plates (K083213)
Synthes USA, Synthes Variable Angle LCP Ankle Trauma System (K120854)
Synthes USA, Synthes 2.7/3.5mm Variable Angle LCP Ankle Trauma System-Anterolateral Distal Tibia Plates (K121601)
Flower Orthopedics Corporation, Flower Small and Medium Implants Set (K123562 and K131657)

**Intended Use / 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.

**Device Description**

The Flower Ankle Plating Set consists of the following components and accessories: distal medial tibia plates, distal lateral tibia plates, distal tibia A-plate, straight fibula plate, distal lateral fibula plate, all made of pure titanium compliant with ASTM F67. The system accepts locking and non-locking screws cleared via K123562 and K131657. The device is provided with general purpose instruments.

**Technological Characteristics**

The Flower Ankle Plating Set consists of the following components/configurations:

- Distal Medial Tibia Plates with a width of 11mm and a length range of 107mm-179mm;
- Distal Lateral Tibia Plates with a width of 11mm and a length range or 81mm-141mm;
- Distal Tibia A-Plate with a width of 11mm and length of 65mm;
- Straight Fibula Plates with a width of 11mm and a length range of 45mm-86mm; and
- Distal Lateral Fibula Plates with a width of 11mm and length range of 84mm-180mm.

**Performance Data**

The Flower Ankle 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 ankle plates provide appropriate mechanical strength for the claimed intended use.

In all instances, the Flower Ankle 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 Ankle 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 Ankle Plating Set provide appropriate mechanical strength for the claimed intended use. Thus, the subject ankle plates are substantially equivalent.

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

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

November 18, 2013

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, "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): K133102

Device Name: Flower Ankle Plating Set

Indications for Use:

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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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices