Impact Medical

MAY 0 1 2014

Impact Medical, LLC 510(k) Summary

Date Prepared: April 29, 2014

Contact Details

Applicant Name: Impact Medical, LLC
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Contact Name

Madalyn Duncan
Regulatory/Quality Contact
1-503-521-7669

Device Information

Type of 510(K): Traditional 510(k)

Device Trade Name: Orthopedic Fixation Systems (OFS)

Device Common Name: Plates: Fixation Bone
Screws: Fixation Bone
Wires

Device Trade Name: Orthopedic Fixation Systems (OFS)

Product Code (s): HRS: Plate, Fixation, Bone
HWC: Screws, Fixation, Bone
HTY: Pin, Fixation, Smooth

Classification Regulation: Title 21 CFR 888.3030: Single/multiple component metallic fixation appliances and accessories
Title 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener

Classification: Class II

Classification Panel: Orthopedics

Legally Marketed Predicate Device (s)

510(k)'s: K110086, K962011, K071035, K061620, K000684, K043185, K021556

Description

The Impact Medical, LLC Orthopedic Fixation Systems (OFS) consists of various plates, screws and K-Wires that can be provided in sets or individually. Sets are designed for a specific plate and screw combination. They are sold Non-Sterile and must be sterilized by the facility according to a validated and monitored hospital or facility protocol prior to use. All plates, screws and wires are made from 316L stainless steel that meets ASTM F138 Standard Specification for Wrought 18-Chromium-14Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673) 2008. The screws are self-tapping and come in various sizes of Cancellous, Cortex, Cannulated, Locking and Headless Compression. Impact Medical, LLC's Orthopedic Fixation System (OFS) of plates, screws and wires are single use only.

Intended Use/Indications for Use

The Impact Medical, LLC screws, plates, and K-Wires are single use, non-sterile and are indicated for use in:

- Fixation and stabilization of fractures in small and long bones; including at a minimum: the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, clavicle, humerus, ulna, middle hand and middle foot bones, calcaneus and for fixation of fractures in the proximal femur and trochanteric, pertrochanteric, intertrochanteric, and basilar neck fractures.
- Kirschner (K) wires are used in support of fracture fixation, for osteotomies in the presence of adequate immobilization and implant guide wires.

Substantial Equivalence Comparison

Impact Medical, LLC Orthopedic Fixation Systems have the same regulatory classification, similar indications for use, similar performance characteristics, and all systems have the same 316L material as the predicates. The devices have been tested in comparison with the predicate and demonstrated to be safe and effective for their intended use.

Non-Clinical Performance and Testing

Impact Medical, LLC has confirmed that their Orthopedic Fixation Systems meet the established requirements and the systems have been tested for compliance with standards in comparison with the predicates. Testing was a combination of Monotonic and cyclic bending tests of plates, insertion/removal, torsion and pullout of screws, and geometric analysis. The product bench and standards comparison testing with the predicates demonstrated that the devices were safe and effective and substantially equivalent to product already on the market.

Clinical Testing

No clinical testing was required nor was performed.

Conclusions

Impact Medical, LLC Orthopedic Fixation Systems have the same intended use, materials and performance characteristics as the predicates. Therefore, Impact Medical, LLC believes the systems to be substantially equivalent to the predicates.

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

May 1, 2014

Impact Medical, LLC
Mr. E.J. Duffy
Chief Executive Officer
10110 SW Nimbus Avenue, Suite B6
Portland, Oregon 97223

Re: K140216
Trade/Device Name: Orthopedic Fixation Systems (OFS)
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, HTY
Dated: April 16, 2014
Received: April 17, 2014

Dear Mr. Duffy:

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

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

Enclosure

Indications for Use

510(k) Number (if known): K140216

Device Name: Orthopedic Fixation Systems (OFS)

Indications for Use:

The Impact Medical, LLC screws, plates, k-wires and are single use, non-sterile and are indicated for use in:

- fixation and stabilization of fractures in small and long bones; including at a minimum : the tibia , fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, clavicle, humerus, ulna, middle hand and middle foot bones, calcaneus and for fixation of fractures in the proximal femur and trochanteric, pertrochanteric , intertrochanter ic, and basilar neck fractures
- Kirschner (K) wires are used in support of fracture fixation, for osteotomies in the presence of adequate immobilization and implant guide wires

Prescription Use ——X—— (Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use ____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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