



Food and Drug Administration
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July 6, 2016

Ascension Orthopedics
% Ms. Jayana Kenana
Regulatory Associate
Integra LifeSciences
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K160830

Trade/Device Name: Integra® External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: June 7, 2016
Received: June 8, 2016

Dear Ms. Kenana:

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 Parts 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,

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)

Device Name

Integra® External Fixation System

Indications for Use (Describe)

The Integra® External Fixation System is an external fixation device intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality. Additional indications for the Integra External Fixation System include:

- Correction of deformity
- Revision procedures where other treatments or devices have been unsuccessful
- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot reconstruction and Lisfranc dislocations
- Ankle distraction (arthrodiastasis)

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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Integra LifeSciences Corporation
Special 510(k)
Integra® External Fixation System

5. 510k Summary

Device Trade Name: Integra® External Fixation System

Date: March 23, 2016

Sponsor: Integra® LifeSciences Corporation

Contact Person:

Integra Life Sciences Corp
Jayana Kenana
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Manufacturer:

Ascension Orthopedics
8700 Cameron Road, Suite 100
Austin, TX 78754
609-936-2657
jayana.kenana@integralife.com

Common Name: External Fixation Device

Device Classification: Class II

Classification Name: Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)

Regulation: 21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories

Device Regulation Panel: Orthopedic

Device Product Code: Orthopedic KTT



Device Description:

The Integra® External Fixation System is a single-use modular external fixator consisting of the following components: rings, foot plates, compression/distraction struts, half-pin bone screws, straight/olive wires, rods, nuts, bolts, clamps, and other modular fixator components. The modifications to the device include material and minor design updates to the Universal Wire Fixation Bolt and Slotted Posts which do not affect the safety and effectiveness of the device. An update was also made to the position of the olive on the 530mm olive wire. Lastly, the sharpness of the olive wire and k-wire were modified.

Implants:

Half-pin Bone Screws

The self-drilling half-pin bone screw is 200mm in length and offered in the following sizes: 4mm diameter w/ 20mm thread length, 4mm diameter w/ 30mm thread length, 4mm diameter w/ 40mm thread length, 5mm diameter w/ 30mm thread length, 5mm diameter w/ 40mm thread length, 5mm diameter w/ 50mm thread length, 6mm diameter w/ 30mm thread length, 6mm diameter w/ 40mm thread length, and 6mm diameter w/ 50mm thread length.

K-wires

The wires are offered in the following sizes: 400mm smooth, 400mm olive, and 530mm olive.

K-wire washer in 1 size

Single Use Components:

Rings

Full Ring– The full ring is offered in the following sizes: 140mm, 160mm, 180mm, and 200mm.

Half Ring– The half ring is offered in the following sizes: 140mm, 160mm, 180mm, 200mm, and 220mm.

5/8" Ring– The 5/8" ring is offered in the following sizes: 140mm, 160mm, 180mm, 200mm, and 220mm.

Cross bar – Two lengths

Foot Plates

The foot plate is offered in the following sizes: 140mm, 160mm, and 180mm.

Struts

Struts are offered in the following lengths: long (180-230mm), medium (140-180mm), and short (95-140mm).

Rocker bottom

K-wire holding bolts

Half pin clamps

Extensions:

Threaded rods (20mm through 200mm, hex posts (20mm through 60mm), cubes (1, 2, 3, and 4 hole)

Miscellaneous components:

Washers, nuts, bolts (10mm through 18mm), universal joint, slotted posts (small and large), and plates (straight and twisted).

Reusable Instruments:

Wire tensioner
Wrenches
Wire cutters
Wire Benders
AO adapters
Holding and alignment Blocks
Drill guide assembly
Drills
Provisional Alignment Guides

Intended Use:

The Integra® External Fixation System is a single-use modular external fixator consisting of rings, half-pin bone screws, wires, and struts and is intended for the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of external fixation.

Indications for Use:

The Integra External Fixation System is an external fixation device intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality. Additional indications for the Integra External Fixation System include:

- Correction of deformity
- Revision procedures where other treatments or devices have been unsuccessful
- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot reconstruction and Lisfranc dislocations
- Ankle distraction (arthrodiastasis)

Technological Characteristics:

There are no technological characteristics that raise new issues of safety or effectiveness.

Assessment of performance data:

The performance of the Integra® External Fixation System was verified to be statistically equivalent to that of the predicate device (Integra External Fixation System, K140463). The



Integra LifeSciences Corporation
Special 510(k)
Integra® External Fixation System

material change done to the wire fixation bolt on the Integra External Fixation System construct were tested both dynamically and statically. The performance testing done on the wire fixation bolt was applied to the material change of the slotted posts to 17-4 SS. The stiffness of the 2 systems was compared and was statistically equivalent. A torsional strength test, static wire retention test, and dynamic wire retention test was performed. Validation was performed on the shift of position of the olive on the olive wire and it was concluded that further verification testing was not needed. Validation was performed on the sharpness of the wires and because this modification has no effect on part strength no further verification testing was performed.

Legally Marketed Predicate Device:

Integra® External Fixation System (K140463)

Predicate Indications for Use:

The Integra® External Fixation System (K140463) is indicated for:

Use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality. Additional indications for the Integra External Fixation System include:

- Correction of deformity
- Revision procedures where other treatments or devices have been unsuccessful
- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot reconstruction and Lisfranc dislocations
- Ankle distraction (arthrodiastasis)

Purpose:

The purpose of this Special 510(k) submission is to gain clearance for the Integra® External Fixation System device modifications including the material change and design updates performed on the Universal Wire Fixation Bolt and Slotted Post. The submission also introduces the minor modifications to the olive location on the olive wire and the sharpness on the olive wire and k-wire.

Based upon the similarities of the Integra External Fixation System and the predicate devices studied, the safety and effectiveness of the Integra External Fixation System is substantially equivalent to the predicate device referenced.

