



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

October 29, 2015

Re: K152527

Trade/Device Name: Integra® Digifuse® Cannulated Intramedullary Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 19, 2015
Received: September 3, 2015

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 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,

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

510(k) Number (if known)
K152527

Device Name
Integra® DigiFuse® Cannulated Intramedullary Fusion System

Indications for Use (Describe)

The DigiFuse® implant is indicated for the fixation of osteotomies and reconstruction of the lesser phalanges during procedures to correct deformities of the toes and fingers.

Indications include:

- Hammer toe deformity
- Claw toe deformity
- Mallet toe deformity
- Other deformities of the feet and hands

The DigiFuse® implants are intended for single use only.

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
 Traditional 510(k)
 Integra® DigiFuse® Cannulated Intramedullary Fusion System

6. 510(k) Summary

Submitter Information – 807.92(a)(1)	
Sponsor Name	Integra LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro, NJ 08536
Name of Contact Person	Jayana Kenana
Phone Number	609-936-2657
Fax Number	609-275-9445
Establishment Registration Number	1651501
Date Prepared	October 21, 2015
Name of Device – 807.92(a)(2)	
Trade of Proprietary Name	Integra® DigiFuse®
Common or Usual Name	Cannulated Intramedullary Fusion System
Classification Name	Smooth & threaded metallic bone fixation fasteners
Classification Panel	Orthopedics
Regulation	Class II, 21 CFR 888.3040
Product Code	HWC
Material	Titanium Alloy (Ti 6Al-4V ELI)
Legally marketed device(s) to which equivalence is claimed – 807.92(a)(3)	
Metasurg DigiFuse Implant – K111536	
OsteoMed Extend 2.0/2.4 Cannulated Screw System – K062863	
NewDeal K-Wire – K022599	
Device Description – 807.92(a)(4)	
The Integra® DigiFuse® Implant is a one-piece threaded device intended to be implanted into the medullary bone of the lesser toes. The implant is offered in several variations consisting of the combination of 2.0mm and 2.5mm, 0° and 10° blades, as well as standard and short blade options.	

Integra LifeSciences Corporation

Traditional 510(k)

Integra DigiFuse Cannulated Intramedullary Fusion System

Intended Use

The DigiFuse® implant is indicated for the fixation of osteotomies and reconstruction of the lesser phalanges during procedures to correct deformities of the toes and fingers.

Indications include:

- Hammer toe deformity
- Claw toe deformity
- Mallet toe deformity
- Other deformities of the feet and hands

The DigiFuse® implants are intended for single use only.

Conclusion:

The Integra® DigiFuse® Implant is composed as the same material as the predicate device from MetaSurg (K111536) and the only difference is the proposed device will be adding two new lengths. The two new lengths are also included in the length range of the predicate device passed by Osteomed (K062863). There are no design, material, or indication differences between the proposed device and predicate devices. Non-clinical evaluation and dimensional analysis was done to confirm substantial equivalence.