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510(K) SUMMARY

DEC 2 1 2012

INTEGRA® Total Foot System

Submitter's name and address:

Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536 USA

Contact person and telephone number:

Stephen Beier
Senior Specialist, Regulatory Affairs
Telephone: 609.936.5436
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Date Summary was prepared:

September 26, 2012

Name of the device:

Proprietary Name: INTEGRA® Total Foot System
Common Name: Plate, Fixation, Bone
Product Code: HRS
Subsequent Product Code: HWC (Screw, Fixation, Bone)
Classification Panel: Orthopedic

Substantial Equivalence:

INTEGRA® Total Foot System is substantially equivalent in function and intended use to the predicate device detailed in the following table.

510(k) Number	Product Code	Trade Name	Manufacturer
K100502	HRS; HWC	Ascension® Total Plate System	Integra LifeSciences Corporation, formally Ascension Orthopedics, Inc.
K091614	HRS; HWC	Osetomed Foot Plating System	Osteomed, L.P.
K094037	KTT	TC Plating System	Orthopro, LLC
K102282	HRS	VariAx Locked Plating System	Howmedica Osteonics Corp
K063049	HRS	Synthes (USA) Modular Mini Fragment LCP System	Synthes (USA)

Device Description:

The INTEGRA® Total Foot System consists of a variety of bone plates and screws intended to be used in fixating fractures, osteotomies, and fusions in the adult foot. The various plate designs are divided into forefoot, midfoot, and rearfoot applications. Plate designs include MPJ fusion, Opening Wedge, Calcaneus, Dwyer, Interpositioning, Lapidus, Reconstruction, 2-10 Hole Tarsalis,

fibula, and fibula tubular plates. Screws include both locking and non-locking designs. All plates and screws are manufactured from ASTM F136 Ti-6Al-4V ELI alloy.

Intended Use:
INTEGRA® Total Foot System is indicated for skeletally mature patients for the following:

- Stabilization and fixation of fresh fractures
- Intra and extra articular fractures, joint depression, and multi-fragmentary fractures
- Revision procedures, joint fusion, and reconstruction of small bones of the feet.

Substantial Equivalence Comparison:
Components of the INTEGRA® Total Foot System are similar in design and materials to the predicate devices: (K100502, K091614, K094037, K102282, and K063049).

Testing and Test Results:
The INTEGRA® Total Foot System and Ascension® Total Foot System (K100502) are both systems comprised of titanium plates and screws with identical indications for use. Additional predicate devices have been included to justify the inclusion of new components to the system.

All new or redesigned components to this system were examined, and results of the verification activities demonstrated that the tests were acceptable and the components substantially equivalent to the predicate devices identified.

Conclusion:
The INTEGRA® Total Foot System is substantially equivalent to the commercially marketed devices, Ascension® Total Foot System (K100502). Additional predicate devices to this system include Osteomed Foot Plating System (K091614), OrthoPro TC Plating System (K094037), Stryker VariAx Locked Plating System (K102282), and the Synthes Modular Mini Fragment LCP System (K063049).

The designs and design modifications expressed in this 510(k) Premarket Notification do not change the intended use or fundamental scientific technology of the predicate devices, nor do they raise any new issues of safety or effectiveness.

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

Integra LifeSciences Corporation
% Mr. Stephen H. Beier
Senior Specialist, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

December 21, 2012

Re: K123000
Trade/Device Name: INTEGRA® Total Foot System
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 26, 2012
Received: September 27, 2012

Dear Mr. Beier:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Peter D. Rumm -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):

Device Name: INTEGRA® Total Foot System

Indications For Use: INTEGRA® Total Foot System is indicated for skeletally mature patients for the following:

- Stabilization and fixation of fresh fractures
- Intra and extra articular fractures, joint depression, and multi-fragmentary fractures
- Revision procedures, joint fusion, and reconstruction of small bones of the feet.

Prescription Use _X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Krishna Asundi
Division of Orthopedic Devices