K093163

INTEGRA
LIFESCIENCES CORPORATION
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DEC 15 2009

510(K) SUMMARY

INTEGRA™ Total Wrist Fusion System

Submitter's name and address:

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Contact person and telephone number

Stephen Beier
Regulatory, Quality, Clinical Affairs Associate
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536, USA
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Email: stephen.beier@Integra-LS.com

Date Summary was prepared:

Monday, October 5, 2009

Name of the device:

Proprietary Name:	INTEGRA Total Wrist Fusion System
Common Name:	Appliance, fixation, nail/blade/plate combination, multiple component, metal composite; Plate, fixation, bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (21CFR 888.3030)
Device Product Code:	LXT; HRS
Classification Panel:	Orthopedic

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Substantial Equivalence:

The INTEGRA™ Total Wrist Fusion System is substantially equivalent to the commercially available devices, Synthes® Wrist Fusion Set, K000558, Synthes® Locking Compression Plate (LCP) Wrist Fusion Set, K042355, and KMI Wrist Fusion System, K991873, which have all been recommended for classification as Class II by the Orthopedic Panel of the Food and Drug Administration. In addition, the Ø3.5mm Surfix® screws utilized in this design were previously cleared through 510(k) K063820 on February 8, 2007.

Device Description:

The INTEGRA Total Wrist Fusion System offers rigid fixation capabilities for the wrist joint of patients utilizing a plate and screw system. The system includes the implant, consisting of the plate and screws, as well as associated instrumentation.

Indications for Use:

The **INTEGRA Total Wrist Fusion System** is indicated for use in patients with:

- Posttraumatic arthritis of the joints of the wrist
- Rheumatoid wrist deformities requiring restoration
- Complex carpal instability
- Post-septic arthritis of the wrist
- Severe unremitting wrist pain related to motion
- Brachial plexus nerve palsies
- Tumor resection
- Spastic deformation
- Pain and/or loss of function due to osteoarthritis
- Revision of failed partial wrist fusions

Testing and Test Results:

Tests have been performed to verify the mechanical suitability of the device. Results demonstrate that the mechanical properties of the INTEGRA Total Wrist Fusion System are substantially equivalent to the predicate devices.

Conclusion

The INTEGRA Total Wrist Fusion System is substantially equivalent to the predicate devices.

The new product does not change the intended use or fundamental scientific technology of the device, nor does it 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 Room W-O66-0609
Silver Spring, MD 20993-0002

Integra LifeSciences Corporation
% Mr. Stephen Beier
Regulatory, Quality, Clinical Affairs Associate
311 Enterprise Drive
Plainsboro, New Jersey 08536

DEC 15 2009

Re: K093163
Trade/Device Name: INTEGRA Total Wrist Fusion 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, LXT
Dated: October 5, 2009
Received: October 6, 2009

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.

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,

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

Enclosure

K093163

Indications for Use

510(k) Number (if known): N/A

Device Name: INTEGRA™ Total Wrist Fusion System

Indications For Use:

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- Tumor resection
- Spastic deformation
- Pain and/or loss of function due to osteoarthritis
- Revision of failed partial wrist fusions

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jonutu for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093163