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DEC 7 2005

newdeal®
An Integra LifeSciences Company

510(k) SUMMARY

A. Submitter's Name and Address:

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ESTABLISHMENT REGISTRATION NUMBER: 9615741

B. Authorized Agent and Official Contact Person:

Judith O'Grady
Sr. VP Regulatory Affairs
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536 USA
Tel: 609-936-2311
Fax: 609-275-9445

C. Date Summary Prepared:

October 31, 2005

D. Name of Device:

Proprietary Name: KALIX® II

Common Name: Screw, Fixation, Bone

Classification Name and Reference:
Smooth or threaded metallic bone fixation fastener (21CFR 888.3040)

Device Product Code: HWC

Proposed Regulatory Class: Class II

Panel: Orthopedic

E. Device Description

The **KALIX® II Flat Foot implant** is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela. This is the same indication for use as the Kalix Implant, K001231.

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F. Indications for Use

The **KALIX II implant** is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

- flat foot treatment in children and adolescents
- congenital flat foot
- non successful long term orthopaedic treatment (shoes, insoles...)
- tarsal coalitions
- painfully flat foot
- supple deformity in posterior tibial tendon dysfunction
- paralytic flat foot
- subtalar instability.

G. Substantial Equivalence

The new KALIX® II implant is substantially equivalent in function and intended to the commercially marketed device, KALIX® implant, K001231.

H. Comparison of Technological Characteristics

The modified KALIX II implant has the following similarities to the unmodified device, KALIX implant, 510(k) K001231:

- Same intended use
- Same materials
- Same basic design
- Same Instructions for Use
- Same manufacturing
- Delivered sterile packaged using the same packaging materials and processes

I. Conclusion

Valid scientific evidence through performance testing provide reasonable assurance that the KALIX® II implant is substantially equivalent to commercially marketed device, KALIX® implant, K001231. The modifications do not change the intended use or fundamental scientific technology of the device and do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 7 2005

Newdeal SAS
c/o Judith O'Grady
Sr. VP Regulatory Affairs
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K053093
Trade/Device Name: KALIX® II flat foot Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Codes: HWC
Dated: October 31, 2005
Received: November 7, 2005

Dear Ms. O'Grady:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053093

Device Name: KALIX® II flat foot implant

Indications For Use:

The **KALIX II implant** is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

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- paralytic flat foot
- subtalar instability.

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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053093