510(k) SUMMARY
Newdeal Panta® Nail (dia. 10mm)
Newdeal Panta® Nail XL

Submitter's name and address:

JUL 2 9 2009

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Date Summary was prepared

June 10, 2009

Name of the devices :

- Proprietary Name: Newdeal Panta® Nail
  Common Name: Ankle nail
  Classification Name: Rod, Fixation, Intramedullary and Accessories (21CFR888.3020)
  Device Product Code: HSB
  Classification Panel: Orthopedic

Substantial Equivalence:

The modified Panta® Nail (dia. 10 mm and XL) is substantially equivalent to commercially marketed device Newdeal Ankle Nail (K050882), Depuy ACE VersaNail (K023115) and BIOMET Ankle Arthrodesis Nail (K021786).

Device description

The modified Panta® Nail (dia. 10mm and XL) is ideally suited for tibiotalocalcaneal fusion indications. These Nails affords rigid, load sharing fixation that incorporates a simple nail-mounted, in-line method of compression across the arthrodesis site.
The Panta® Nail (dia. 10mm and XL) affords even more torsional rigidity and better calcaneal purchase through its two transcalcaneal locking screws that are inserted from posterior to anterior, using a nail-mounted targeting device. Calcaneal screws eliminate significant rotation, preventing the calcaneus from "rocking" on the nail during weight-bearing. Some screws allow a sufficient stability for the fixation between calcaneus, talus and tibia.
The Panta® Nail (dia. 10mm and XL) is provided with sterile end caps which sit flush to the end of the nail and protect the internal threads from tissue ingrowth.

Intended Use

The PANTA® Nail system is intended for use in tibiotalocalcaneal arthrodesis and treatment of trauma to the hindfoot and distal tibia. Examples include:

- Post-traumatic and degenerative arthritis involving both ankle and subtalar joints
- Rheumatoid arthritis
- Revision of failed ankle arthrodesis with subtalar involvement or with insufficient talar body
- Revision of failed total ankle arthroplasty with subtalar intrusion
- Talar deficiency conditions (requiring a tibiocalcaneal arthrodesis)
- Avascular necrosis of the talus
- Neuroarthropathy or neuropathic ankle deformity
- Severe deformity as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease
- Severe pilon fractures with trauma to the subtalar joint.

Testing and Test Results:

Mechanical tests have been carried out. Results have shown that the mechanical properties of the modified Panta® Nail (dia. 10mm and XL) is equivalent to the properties of the unmodified device Newdeal Ankle Nail, K050882.

Conclusion

The modified Newdeal Panta® Nail (dia. 10mm and XL) is subsequently equivalent to commercially marketed device, Newdeal Ankle Nail (K050882), Depuy ACE VersaNail (K023115) and BIOMET Ankle Arthrodesis Nail (K021786).

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

Newdeal SAS
% Mr. Frederic Testa
Sr. Regulatory Affairs Project Manager
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536

JUL 29 2009

Re: K091788
Trade/Device Name: Newdeal Panta® Nail (10 mm and Panta® Nail XL) System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: July 8, 2009
Received: July 9, 2009

Dear Mr. Testa:

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" (21 CFR 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

Indications for Use

510(k) Number (if known) : K091788

Device Name: **Panta® Nail**

- Indications For Use: **Panta® Nail**

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

for MXM

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

510(k) Number K091788