K050882

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newdeal®
An Integra LifeSciences Company

MAY 27 2005

510(k) SUMMARY

A. **Applicant's Name and Address:**
Newdeal SA
An Integra LifeSciences Company
10, place d'Helvétie
69006 LYON
FRANCE
Tel.: +33 4 37 47 51 51
Fax: +33 4 37 47 51 52
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:**
April 6, 2005

D. **Name of Device:**
Proprietary Name: Newdeal Ankle Nail

Common Name: Ankle nail

Classification Name and Reference:
Intramedullary fixation rod (21 CFR 888.3020)

Device Product Code: HSB

Proposed Regulatory Class: Class II

Panel: Orthopedic

E. **Device Description**
The Newdeal Ankle Nail is a straight, cannulated intramedullary nail available in diameters of 11mm, 12mm and 13mm, and lengths of 150mm and 180mm. Holes in the nail allow for proximal and distal locking, using locking cortical screws 5mm diameter, 20 to 110mm long by 5mm increment.
The Newdeal Ankle Nail, the end cap and the locking screws are all made from Ti-6Al-4V ELI alloy.

The Newdeal Ankle Nail is to be implanted by insertion through the calcaneus, the talus, into the distal tibia, for tibiotalocalcaneal arthrodesis, for correction of deformity, or fixation of fractures.

F. Indications for Use

The **Newdeal Ankle Nail** 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

G. Substantial Equivalence

The **Newdeal Ankle Nail** is substantially equivalent in terms of design, material, indications for use and dimensions with the following predicate devices:

Smith & Nephew	ReVision Nail	K983942
DePuy	VersaNail	K023115
Biomet	Ankle Arthrodesis Nail	K021786

H. Comparison of Technological Characteristics

The technological characteristics of the **Newdeal Ankle Nail** are the same as the characteristics of predicate devices in terms of intended use and design. All of these nails have the following characteristics:

- Holed for proximal and distal locking
- Made from Titanium alloy or stainless steel
- Cannulated
- Equivalent size range
- Intended to be implanted for tibiocalcaneal arthrodesis

I. Summary of Studies

Torsion, compression and bending tests have been carried out. The Newdeal Ankle Nail meets our acceptance criteria.

J. Conclusion

The Newdeal Ankle Nail is substantially equivalent to the predicate devices Smith & Nephew ReVision nail, K983942, DePuy ACE VersaNail, K023115 and Biomet Ankle Arthrodesis Nail, K021786.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2005

Newdeal SA
C/o Ms. Judith E. O'Grady
Senior V.P Regulatory Affairs
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K050882
Trade/Device Name: Newdeal Ankle Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: April 6, 2005
Received: April 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,

Miriam C. Provost, Ph.D.
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):

Device Name: NEWDEAL ANKLE NAIL

Indications For Use:

The **Newdeal Ankle Nail** 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

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, [illegible]
and Neurological De[illegible]

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