newdeal®
An Integra LifeSciences Company

MAR 17 2005

K050396

510(k) SUMMARY

A. **Submitter's Name and Address:**

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FRANCE
Tel.: +33 4 37 47 51 51
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ESTABLISHMENT REGISTRATION NUMBER: 9615741

B. **Contact Person:**

Morgane GRENIER
Regulatory and Clinical Affairs Manager
Newdeal SA
10, place d'Helvétie
69006 LYON
FRANCE
Tel: +33 4 37 47 51 51
Fax: + 33 4 37 47 51 52

C. **Date Summary Prepared:**
February 4, 2005

D. **Name of Device:**
Proprietary Name: STABILIZATION SCREW

Common Name: Bone fixation screw

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

Device Product Code: HWC

Proposed Regulatory Class: Class II

Panel: Orthopedic

E. **Device Description**
The **STABILIZATION SCREW** is a cannulated compression screw with a non-threaded shaft, allowing optimal compression. It also has a self-tapping screw tip. It is provided in diameters 3.0 mm and 4.3 mm and in length from 10 mm to 34 mm for the 3 mm and from 22 mm to 60 mm for the 4.3 m. The **STABILIZATION SCREW** is made from Titanium alloy (Ti-6Al-4V ELI).

F. Indications for Use

The **STABILIZATION SCREW** is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Mono or Bi-cortical osteotomies in the foot or hand (including Hallux Valgus treatment)
- Fractures management in the foot or hand
- Fixation of bone fragments in long bones or small bones fractures
- Arthrodesis in hand, foot or ankle surgery

The size of the chosen screw should be adapted to the specific indication.

G. Substantial Equivalence

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

3.0 mm STABILIZATION SCREW:

Newdeal	BOLD® screw	K011262
DePuy	Scarf Thread-Head Screw	K971070

4.3 mm STABILIZATION SCREW:

Newdeal	4.0 mm I.CO.S.® Screw	K011821
Synthes	4.5 mm Cannulated Screw	K963172

H. Comparison of Technological Characteristics

The technological characteristics of the **STABILIZATION SCREW** are the same as the characteristics of predicate devices in terms of intended use and design. All of these screws have the following characteristics:

- self-tapping
- cannulated
- made from Titanium alloys
- non-threaded part allowing compression between two bone fragments
- equivalent size range
- indicated for fixation of bone fractures or for bone reconstruction

I. Summary of Studies

Torsional and pullout strength tests have been carried out following the ASTM F543-02 standard *(Standard Specification and Test Methods for Metallic Medical Bone Screws)*. 3-point bending tests have also been realized. Results have shown that mechanical properties of the **STABILIZATION SCREW** are equivalent to the predicate devices.

J. Conclusion

The 3.0 mm STABILIZATION SCREW is substantially equivalent to the predicate devices NewDeal Bold® Screw, K011262, DePuy Scarf Thread-Head Screw, K971070, and the 4.3 mm STABILIZATION SCREW is substantially equivalent to NewDeal I.CO.S® Screw, K011821 and Synthes 4.5 mm Cannulated Screw, K963172.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2005

Ms. Morgane Grenier
Regulatory and Clinical Affairs Manager
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K050346
Trade/Device Name: Stabilization Screw
Regulation Numbers: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Codes: HWC
Dated: March 28, 2005
Received: April 27, 2005

Dear Ms.Grenier:

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 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: STABILIZATION SCREW

Indications For Use:

The **STABILIZATION SCREW** is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Mono or Bi-cortical osteotomies in the foot or hand (including Hallux Valgus treatment)
- Fractures management in the foot and hand
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- Arthrodesis in hand, foot or ankle surgery

The size of the chosen screw should be adapted to the specific indication.

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)

for Mark N Milhous

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

510(k) Number K050346 **A-001**