K052152 p/2

newdeal®
An Integra LifeSciences Company

SEP 1 3 2005

510(k) SUMMARY

A. Submitter's Name and Address

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ESTABLISHMENT REGISTRATION NUMBER: 9615741

B. Contact Person

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Regulatory and Clinical Affairs Manager
Newdeal SAS
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FRANCE
Tel: +33 4 37 47 51 51
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C. Date Summary Prepared

August 1, 2005

D. Name of Device

Proprietary Name: B-BOP® plate

Common Name: Plate, fixation, bone

Classification Name and Reference

Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)

Device Product Code: HRS

Proposed Regulatory Class: Class II

Panel: Orthopedic

E. Device Description

In the case of significant deformities (Hallux Valgus, Hallux Varus) of the forefoot, the basal or proximal osteotomy is generally more indicated than the distal osteotomy allowing greater corrections of the 1st metatarsal.

Newdeal has developed a plate dedicated to the fixation of basal osteotomy of the 1st metatarsal by designing the **B-BOP® plate** which allow to meet at best the specifications of that kind of surgical procedure.

Characteristics of the plate have taken into account all the requirements associated with basal osteotomy:

- Plantar positioning to obtain the best stability and resistance and allowing to reduce bulk
- Anatomical shape adapted to the plantar curve of the 1st metatarsal (pre-bent), available in right or left side and in two angulations (5° and 10°) for medium or large deformation.

The B-BOP® plate is made from titanium alloy (Ti-6Al-4V ELI) and the part of the plate in contact with bone is sandblasted for a better adherence of the plate.

Plates and screws are also available which are color-coded for ease of identification.

Fixation of the plate is provided by four Snap-Off screws, already present with the HALLU®-Fix system (cleared under K021626).
With the B-BOP® plate, screws are available in 2 diameters (2.7mm and 3.0mm) and in a length range from 14mm to 26mm (2 mm increment). The screws are provided sterile with the B-BOP® plate.

F. Indications for Use

The **B-BOP® plate** is intended for fixation of osteotomy of the basis of the first metatarsal. Examples include:

- Moderate to severe hallux valgus
- Hallux varus

G. Substantial Equivalence

The B-BOP® plate is substantially equivalent in terms of design, material, indications for use and fixation with the following predicate devices:

Arthrex	Small Fragment Plates and Screws	K040907
Acumed	Congruent Bone Plate System	K012655
Synthes	Modular Foot System	K001941

H. Comparison of Technological Characteristics

The technological characteristics of the **B-BOP®** plate are the same as the characteristics of predicate devices in terms of intended use and design.
All of these plates have the following characteristics:

- Holed for screwed fixation
- Made from Titanium alloy or stainless steel

- Equivalent size range
- Intended to be implanted for fixation of osteotomies, including basal osteotomy of the metatarsal.

I. Summary of Studies

Bending strength test and fatigue testing have been carried out. The B-BOP® plate meets our acceptance criteria.

J. Conclusion

The **B-BOP® plate** is substantially equivalent to commercially marketed devices, the Arthrex Small Fragment Plates and Screws (K040907), the Acumed Congruent Bone Plate System (K012655) and the Synthes Modular Foot System (K001941).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2005

Newdeal SAS
c/o Ms. Judith E. O'Grady
Integra Lifesciences
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K052152
Trade/Device Name: B-BOP® plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: August 1, 2005
Received: August 9, 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.

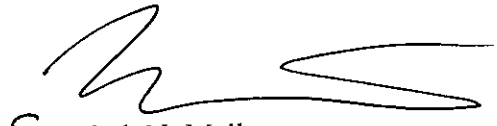
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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/dsma/dsmamain.html

Sincerely yours,



for 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): K052152

Device Name: B-BOP® plate

Indications For Use:

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- Moderate to severe hallux valgus
- Hallux varus

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 K052152