K091609 #1/2

newdeal®
An Integra LifeSciences Company

JUN 30 2009

510(K) SUMMARY

Newdeal Compression Plate

Submitter's name and address:

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Contact person and telephone number

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Alternate Contacts
Authorized Agent in the United States

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Date Summary was prepared:

May 28, 2009

Name of the device:

Proprietary Name:	Newdeal Compression Plate
Common Name:	Plate, Fixation, Bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (21CFR 888.3030)
Device Product Code:	HRS
Classification Panel:	Orthopedic

K091609 #2/2

Substantial Equivalence:

The modified Newdeal Compression Plate is substantially equivalent to commercially marketed device, Newdeal Compression Plate, K070447.

Device Description:

The Newdeal Compression Plate will offer the combination of two concepts:

- By widening the "eye" (diamond shaped opening) on the interaxis of the plate, mechanical deformation leads to narrowing of the interaxis of the two legs and thus provides compression between the two bone fragments to fuse. This is the same principle as the Newdeal Compression Plate (K070447), UNI-CLIP (K011716) and Newdeal Large UNI-CLIP (K061594).
- The rigidity of the "legs" is obtained using the Newdeal Locking System including a screw and a washer. This is the same principle as the Locking System of the following predicate devices: Surfix Knee Osteotomy System (K041601), Newdeal Lisfranc Plates (K060474), Newdeal Lapidus Plates (K060476), Newdeal TTC Plates (K060473 and Newdeal Compression Plate (K070447).

Intended Use:

The **Newdeal Compression Plate** is intended for fixation of bone fractures or for bone reconstruction.

Examples include:

- Arthrodesis in hand or foot surgery
- Fracture management in the foot or hand
- Mono or Bi-cortical osteotomies in the foot or hand
- Distal or proximal metatarsal or metacarpal osteotomies
- Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc)

The size and number of the plate(s) used should be adapted to the specific indication.

Testing and Test Results:

Mechanical tests have been carried out. Results have shown that the mechanical properties of the modified Newdeal Compression Plate are equivalent to the properties of the unmodified device, Newdeal Compression Plate, K070447.

Conclusion

The modified Newdeal Compression Plate is substantially equivalent to commercially marketed device, Newdeal Compression Plate, K070447.

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

JUN 30 2009

Newdeal SAS
% Ms. Judith E. O'Grady
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K091609
Trade/Device Name: Newdeal Compression 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: May 28, 2009
Received: June 03, 3009

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 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/cdrh/comp/ 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" (21CFR 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

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): K091609

Device Name: **Newdeal Compression Plate**

Indications For Use:

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- Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc)

The size and number of the plate(s) used should be adapted to the specific indication.

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)

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

510(k) Number K091609