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510(K) SUMMARY

Newdeal Compression Plates

MAR 29 2007

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Date Summary was prepared:

February 9, 2007

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

Substantial Equivalence:

The **Newdeal Compression Plate** is substantially equivalent to the Wright Medical Technology Compression Plate, K051908 and the Newdeal Large UNI-CLIP Staple, K061594.

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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 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 device: Surfix Knee Osteotomy system (K041601), Newdeal Lisfranc Plates (K060474), Newdeal Lapidus Plates (K060476) and Newdeal TTC Plates (K060473).

The plate will be available with 2 or 4 holes and with interaxis of 20, 25 or 30 mm.

Fixation of the Newdeal Compression Plate is provided by two or four Screws & washers, which are the same as for the Lapidus Plate (K060474) and Lisfranc Plate (K060476).

Plates, screws and washers will be provided either sterile or non-sterile.

The Locking System (Screw + washer) will be made from Titanium alloy Ti-6Al-4V or 316L Stainless Steel.

Intended Use:

The Newdeal Compression Plate is indicated for fixation of bone fractures or for bone reconstruction.
Examples include:

- Arthrodesis in hand or foot surgery
- Fractures 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 plate(s) used should be adapted to the specific indication.

Testing and Test Results:

Mechanical tests have been carried out and results were compared with the predicate device, Large UNI-CLIP (K061594).

All the results show us that the Newdeal Compression Plate have mechanical properties compatible with their intended uses.

Conclusion

The Newdeal Compression Plate is substantially equivalent to commercially marketed devices, the Wright Medical Technology Compression Plate, K051908 and the Newdeal Large UNI-CLIP Staple, K061594.

The Newdeal Compression Plate does not raise any new issues of scientific technology, safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

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Re: K070447
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: February 9, 2007
Received: February 15, 2007

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

Sincerely yours,

Mark N. Melkerson
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): K070447

Device Name: Newdeal Compression Plate

Indications For Use:

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The size and number of plate(s) used 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)

Barbara Buchup

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

510(k) Number K070447