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newdeal®
An Integra LifeSciences Company

510(K) SUMMARY

Newdeal HALLU® Lock Plate System

JUL 10 2009

Submitter's name and address:

Newdeal SAS
10, place d'Helvétie
69006 Lyon, France
Tel: +33 4 37 47 51 51
Fax: +33 4 37 47 51 52

Contact person and telephone number

Morgane Grenier
Director of Regulatory and Clinical Affairs - EMEA
Newdeal SAS
10, place d'Helvétie
69006 Lyon, France
Tel: +33 4 37 47 51 51
Fax: +33 4 37 47 51 52

Alternate Contacts
Authorized Agent in the United States

Judith E. O'Grady, RN, MSN
Sr. Vice President, Regulatory Affairs, Quality Assurance and Clinical Affairs
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536, USA
Tel: (609) 936-2311
Fax: (609) 275-9445
E-mail: jogrady@integra-ls.com

Date Summary was prepared:

July 7, 2009

Name of the device:

Proprietary Name:	Newdeal HALLU® Lock Plate System
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

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Substantial Equivalence:

The modified HALLU® Lock Plate System is substantially equivalent to commercially marketed device, HALLU® Plate System, K021626

Device Description:

The Newdeal HALLU® Lock Plate System is a low profile Titanium plate dedicated to first metatarso-phalangeal arthrodesis. The HALLU Lock C plates are pre-bent with 10° valgus and 10° dorsiflexion. The HALLU Lock S plates are available with 10° valgus and 10° or 5° dorsiflexion. Pre-operative bending is possible to completely fit to the anatomical shape of the joint. Their fixation is provided by SURFIX and SURFIX ALPHA locking screws.

Intended Use:

The HALLU® Lock Plate System is intended to be implanted for fixation of fractures, osteotomies or arthordesis of the first metatarso-phalangeal joint, including cases of :

- Hallux rigidus
- Severe hallux valgus (IM angle >20° and HV angle > 40°)
- Deformity from rheumatoid arthritis
- Failed previous surgical procedure
- Traumatic arthritis
- Neuromuscular instability.

Addition of a Newdeal® QWIX® screw crossing the joint is strongly recommended for optimal arthrodesis consolidation.

HALLU® Lock Newdeal® plates must be fixed with the Surfix® fixed angle locking system and with the Surfix® -Alpha variable angle locking system of 2.7mm or 3.0mm diameter (screws and lock-screws).

Testing and Test Results:

Mechanical tests have been carried out. Results have shown that the mechanical properties of the modified HALLU® Lock Plate System are equivalent to the properties of the unmodified device, HALLU® Plates, K021626.

Conclusion

The modified HALLU® Lock Plate System is substantially equivalent to commercially marketed device, HALLU® Plates, K021626.

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

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

JUL 10 2009

Re: K083154
Trade/Device Name: HALLU Lock Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: June 10, 2009
Received: June 11, 2009

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,

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): K083154

Device Name: **HALLU® Lock Plates**

Indications For Use:

The **HALLU® Lock Plates** are intended for fixation of fractures, osteotomies or arthrodesis of the first metatarso-phalangeal joint. Including cases of:

- Hallux rigidus
- Severe hallux valgus (IM angle >20° and HV angle >40°)
- Deformity from rheumatoid arthritis
- Failed previous surgical procedure
- Traumatic arthritis
- Neuromuscular instability.

The HALLU® Lock plates must be fixed with the SURFIX® fixed angle locking system and with the SURFIX®-Alpha variable angle locking system of 2.7mm or 3.0mm diameter (screws and lock-screws).

Addition of a Newdeal® QWIX® screw crossing the joint is strongly recommended for optimal arthrodesis consolidation

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 K083154