K061594

JUL - 3 2006

newdeal®
An Integra LifeSciences Company

510(k) SUMMARY

A. **Submitter's Name and Address:**
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10, place d'Helvétie
69006 LYON
France
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ESTABLISHMENT REGISTRATION NUMBER: 9615741

B. **Contact Person:**
Morgane GRENIER
Regulatory and Clinical Affairs Manager
Newdeal SAS
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:**
June 7, 2006

D. **Name of Device:**
Proprietary Name: LARGE UNI-CLIP® STAPLES

Common Name: Staple, fixation, bone

Classification Name and Reference:
Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)

Device Product Code: JDR

Proposed Regulatory Class: Class II

Panel: Orthopedic

E. **Device Description**
The LARGE UNI-CLIP® STAPLE is a staple so that, by widening the diamond shaped opening, mechanical deformation leads to narrowing of the interaxis of the two legs.
The surgeon can obtain a true compression, adjustable and controlled with many choice of size.

The LARGE UNI-CLIP® STAPLE is made from 316L Stainless Steel that conforms to ISO 5832-1 and ASTM F138 & F139 standards.

F. Indications for Use

The LARGE UNI-CLIP® STAPLE 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 staple(s) used should be adapted to the specific indication.

G. Substantial Equivalence

The new LARGE UNI-CLIP® staples are substantially equivalent to commercially marketed device, UNI-CLIP® staples, K011716.

H. Comparison of Technological Characteristics

The modified device has the same fundamental scientific technology and intended uses as the predicate device.
The modified staple has the following similarities to those which previously received 510(k) concurrence:

- Same intended use
- Same materials
- Same Instructions for Use
- Same basic design
- Same manufacturing process

I. Summary of Studies

Mechanical tests have been carried out. Results have shown that the mechanical properties of the LARGE UNI-CLIP® staples are thus similar to the properties of the unmodified device, UNI-CLIP® staples, K011716.

J. Conclusion

The new LARGE UNI-CLIP® staples are substantially equivalent to commercially marketed device, UNI-CLIP® staples, K011716.

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

JUL - 3 2006

Newdeal SAS
% Integra LifeSciences Corporation
Ms. Judith E. O'Grady
Sr. Vice President, Regulatory and Clinical
Affairs, Quality Assurance
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K061594
Trade/Device Name: The LARGE UNI-CLIP®
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulation Class: II
Product Code: JDR
Dated: June 7, 2006
Received: June 9, 2006

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

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,

for

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):

Device Name: LARGE UNI-CLIP®

Indications For Use:
The LARGE UNI-CLIP® is indicated for fixation of bone fractures or for bone reconstruction.
Examples include:

- Arthrodesis in hand or foot surgery
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The size and number of staple(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)

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

510(k) Number K061594