JUN 3 1999

K991482

NEWDEAL SA • 31 RUE DE LA CONVENTION
PARC D'ACTIVITÉS GARIGLIANO
38200 VIENNE • FRANCE
TEL : (33) 04 74 78 15 15
FAX : (33) 04 74 78 15 16
INTERNET EMAIL : NEWDEALFR@AOL.COM

3. SUMMARY OF SAFETY AND EFFECTIVENESS

A. SPONSOR IDENTIFICATION:

NewDeal SA
Parc d'Activitiés Garigliano
Rue de la Convention
38 200 VIENNE
FRANCE

Tél. : (33) 4 74 78 15 15
Fax : (33) 4 74 78 15 16

B. ESTABLISHMENT REGISTRATION NUMBER: Pending

C. OFFICIAL CONTACT PERSON

Norman F. Estrin, Ph. D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac , MD 20854

Tel. : (301) 279 -2899
Fax : (301) 294-0126

D. DATE OF PREPARATION OF THIS SUMMARY: April 26, 1999

E. PROPRIETARY (TRADE) NAME: **UNI-CLIP® STAPLE**

F. COMMON NAME: Bone fixation staple
True compression, adjustable and controlled.

G. CLASSIFICATION NAME AND REFERENCE:
Staple, Fixation, Bone (21 CFR, Section 888.3040)

H. PROPOSED REGULATORY CLASS: Class II

I. DEVICE PRODUCT CODE: 87JDR

J. PANEL CODE: 21CFR par. 888.3030

DESCRIPTION OF DEVICE:

The **UNI-CLIP® STAPLE** is designed so that, by widening the "diamond", mechanical deformation leads to narrowing of the interaxis of the two legs. The surgeon can obtain a true compression, adjustable and controlled, with many choices of size.

INTENDED USE:

The **UNI-CLIP® STAPLE** is implanted for fixation of bone fractures or for bone reconstructions.

INDICATIONS FOR USE:

The **UNI-CLIP® STAPLE** is indicated for:

- Mono or bi-cortical osteotomies in the forefoot
- Distal or proximal metatarsal osteotomies
- Fusion of the first metatarsophalongeal joint and the interphalangeal joint
- Fixation of the osteotomies for hallux valgus treatment (such as, Scarf, Chevron)
- Akyn type Osteotomy
- Arthrodesis base first metatarsal cuneiform joint to reposition and stabilize metatarsus varus primus
- Arthrodesis and osteotomy fixation in the Midfoot and Hindfoot

PREDICATE DEVICE:

The **UNI-CLIP® STAPLE** is substantially equivalent to Memory Staple from DePuy, Inc.(K964226) .

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Both the **UNI-CLIP® STAPLE** have the same intended of use and all are indicated for fixing small fractures or osteotomies. All are made from stainless steel.

SUMMARY OF STUDIES

Torque of divergence and strenght of compression the **UNI-CLIP® STAPLE** was studied and found to have a resistance to torsion in compliance with the selected standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 1999

Norman F. Estrin, Ph.D., RAC
President
Estrin Consulting Group, Inc.
Representing NewDeal SA
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K991482
Trade Name: UNI-CLIP® Staple
Regulatory Class: II
Product Code: JDR
Dated: April 27, 1999
Received: April 28, 1999

Dear Dr. Estrin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CONFIDENTIAL

510(k) Number (if known): K991482

Device Name: **UNICLIP® STAPLE**

Indications for Use:

- Mono or bi-cortical osteotomies in the forefoot
- Distal or proximal metatarsal osteotomies
- Fusion of the first metatarsophalongeal joint and the interphalangeal joint
- Fixation of the osteotomies for hallux valgus treatment (such as, Scarf, Chevron)
- Akyn type Osteotomy
- Arthrodesis base first metatarsal cuneiform joint to reposition and stabilize metatarsus varus primus
- Arthrodesis and osteotomy fixation in the Midfoot and Hindfoot

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X MWM 4/21/99 OR Over-the-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991482

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