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SEP - 8 2004

K041786

3. SUMMARY OF SAFETY AND EFFECTIVENESS

A. SPONSOR IDENTIFICATION:

NewDeal SA
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69006 LYON
FRANCE

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B. ESTABLISHMENT REGISTRATION NUMBER: 9615741

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
estrin@yourFDAconsultant.com

D. PROPRIETARY (TRADE) NAME: **CALCANEA™-PLATE**

E. COMMON NAME: Plate for calcaneal fracture

F. CLASSIFICATION NAME AND REFERENCE

Plate, Fixation, Bone (21 CFR, Section 888. 3030)

G. PROPOSED REGULATORY CLASS: Class II

H. DEVICE PRODUCT CODE: HRS

I. PANEL CODE: 87 OR Orthopedic

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J. DESCRIPTION OF DEVICE:

The CALCANEA^{TM}-PLATE is a Titanium low profile anatomical plate dedicated for fixation of calcaneal fractures.
The CALCANEA^{TM}-PLATE enables a reconstruction of height and width of the calcaneus and a possible remodeling to the lateral calcaneus.
Its anatomical design provides optimal bone coverage while its low profile provides a minimal irritation of soft tissues.

The CALCANEA^{TM}-PLATE is available in three different sizes (1-2-3) for optimal anatomical fit. Numerous holes enable a versatile screw fixation.

The fixation is provided by Titanium screws available in two different design : locking screws and variable angle screws.
The locking screws have threaded heads adapted to the threaded holes of the plate whereas the other design provides a variable angle for a versatile fixation.

The range of screws include a diameter of 3.5 mm and a length from 20 mm to 45 mm (by 5 mm). The fixation screws are self tapping with a smooth tip to protect soft tissues. The screw head design enables a low profile screw/plate/bone interface.

Both plates and screws present a color code for size identification. The lot number and the reference are marked for easier product traceability.

K. INDICATIONS FOR USE: The **CALCANEA^{TM}-PLATE** is indicated for use in fixation of fractures or osteotomies of the calcaneus.

L. PREDICATE DEVICE: The **CALCANEA^{TM}-PLATE** is similar in design and function to the predicates **SYNTHES** Locking Calcaneal Plates **(K991407 – K020401)** and **the DEPUY ACE Calcaneal Peri-Articular Plate (K993465 – K981775).**
Based on the information provided in this premarket notification, Newdeal considers the subject devices to be equivalent to the existing DePuy Ace and Synthes calcaneal plates.

M. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS: The **CALCANEA^{TM}-PLATE**, the **Synthes Locking calcaneal plates and the DePuy ACE calcaneal plate** have same intended of use and are indicated for fixation of

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fractures and osteotomies of the calcaneus.

Both of **CALCANEA™-PLATE** and **DePuy ACE calcaneal plate** in Titanium alloy TIA16V4 whereas the **Synthes locking calcaneal plates** are manufactured in Stainless steel 316 L.

-All those systems are fixed with 3.0mm, 3.5mm or 4.0mm screws.

N. SUMMARY

OF STUDIES:

Determination of the mechanical characteristics (torsion strength, bending strength, comparison with a predicate) of the **CALCANEA™-PLATE** was conducted.

The various tests performed on the **CALCANEA™ Plate** were satisfactory and allow marketing this device, which has mechanical characteristics at least as good as the ones of the competitors, among which the Synthes Calcaneus Locking Plate (K991407) defined as a predicate.

DATE OF PREPARATION OF THIS SUMMARY: June 28, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

NewDeal S.A.
C/o Norma F. Estrin, PhD, RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K041786
Trade/Device Name: CALCANEA™ - 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: June 28, 2004
Received: July 6, 2004

Dear Dr. Estrin:

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.

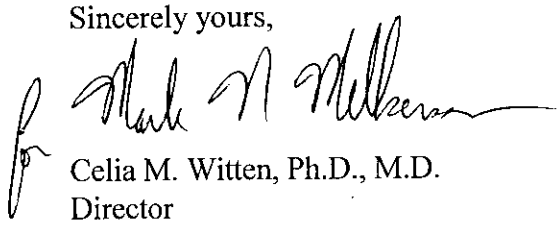
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

510(k) Number (if known): K041784

Device Name: CALCANEA™ -PLATE

Indications for Use:

The CALCANEA™ -PLATE is indicated for use in fixation of fractures or osteotomies of the calcaneus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)

Mark A Millerson

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

510(k) Number K041786

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