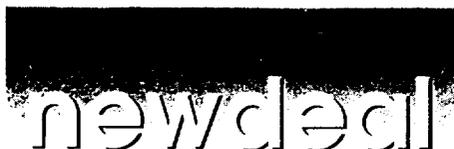


AUG - 3 1999



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

K991566

3. SUMMARY OF SAFETY AND EFFECTIVENESS

A. SPONSOR IDENTIFICATION

NewDeal SA
Parc d'Activités 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 16, 1999

E. PROPRIETARY (TRADE) NAME: SOLUSTAPLE®

F. COMMON NAME: Bone fixation staple

G. CLASSIFICATION NAME AND REFERENCE: (21 CFR, Section 888.3030)

H. PROPOSED REGULATORY CLASS: Class II

I. DEVICE PRODUCT CODE: 87JDR

J. PANEL CODE: 21 CFR par. 888.3030

K. DESCRIPTION OF DEVICE:

The SOLUSTAPLE® is a staple with two self-drilling tips. The treatment with a Solustaple allow, after possible treatment of the second ray, to recreate a square or Greek foot. Two types of staples are available. In order to safeguard the fonction of the joint, the staple with oblique design will be used.

L. INTENDED USE:

The SOLUSTAPLE® is intended to be implanted for fixation of bone fractures or for bone reconstructions.

M. INDICATIONS FOR USE:

The SOLUSTAPLE® is indicated for:

- Akin type osteotomy

N. PREDICATE DEVICE:

The SOLUSTAPLE® is substantially equivalent to the Depuy, inc Varisation Staple.

O. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Both the SOLUSTAPLE®, the Depuy, inc Varisation Staple are made in stainless steel according to ASTM F138 & F139 for bone fixation.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 1999

Norman F. Estrin, Ph.D., RAC
President
Estrin Consulting Group, Inc.
Representing New Deal S.A.
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K991566
Trade Name: Solustaple®
Regulatory Class: II
Product Code: JDR
Dated: May 4, 1999
Received: May 5, 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 control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

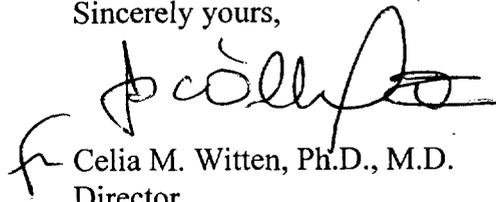
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Dr. Norman F. Estrin

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 at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "C. Witten", is written over the typed name.

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

510(k) Number (if known): K991566

Device Name: SOLUSTAPLE®

Indications for Use:

The SOLUSTAPLE® is indicated for:

- Akin type osteotomy

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

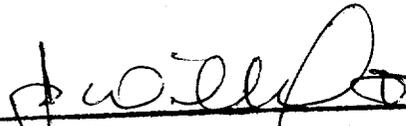
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991566

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