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JUL 14 1999

K991477

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 15, 1999

E. PROPRIETARY (TRADE) NAME: **SPIN® SNAP-OFF SCREW**

F. COMMON NAME:

Bone fixation screw, Self drilling and self tapping snap-off screw

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G. CLASSIFICATION NAME AND REFERENCE
Smooth or threaded metallic bone fixation fastener (21 CFR, Section 888.3040)

H. PROPOSED REGULATORY CLASS: Class II

I. DEVICE PRODUCT CODE: 87HWC

J. PANEL CODE: 21 CFR par. 888.3040

K. DESCRIPTIONOF DEVICE:

The SPIN® SNAP-OFF Screw is a self drilling and self tapping snap-off screw. One part is fixed on a standard surgical power equipment and when the snap-off screw is totally introduced in the bone, its head is blocked and the breaking torque is enough important to cause dissociation between the screw and the snap-off. It comes in lengths from 11 to 14 mm.

L. INTENDED USE:

The **SPIN® SNAP-OFF Screw** is intended to be implanted for fixation of bone fractures or for bone reconstructions.

M. INDICATIONS FOR USE:

The **SPIN® SNAP-OFF Screw** is indicated for fixing the elective osteotomies of the mid-foot bones and the metatarsal and phalanges of the foot only. Examples include:

-Weil osteotomy
- Unicortical small bone fixation

N. PREDICATE DEVICE:

The **SPIN® SNAP-OFF Screw** is substantially equivalent to the Depuy **Twist-off Screw**, the Howmedica **Luhr Screw system**, the Synthes **Cortex Screw** and the **Osteomed M3 Screw.**

O. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Both the **SPIN® SNAP-OFF Screw** and the predicate devices have the same intended use and all are indicated for fixing small fractures or osteotomies. All are made from titanium alloys. The **Twist-off Screw**, the **Luhr Screw system**, and the **Osteomed M3 Screw** are self tapping. The **SPIN® SNAP-OFF Screw andTwist-off Screw** have a cleavable part. Both supply instrumentation sets.

P. SUMMARY OF STUDIES:

Rupture torque of the. **SPIN® SNAP-OFF SCREW** was compared with requirement of the French Standard NF-F 90414 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

JUL 14 1999

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

Re: K991477
Trade Name: Spin® Snap-Off Screw
Regulatory Class: II
Product Code: HWC
Dated: April 26, 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,

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): K991477

Device Name: **SPIN® SNAP-OFF SCREW®**

Indications for Use:

The **SPIN® SNAP-OFF SCREW®** is indicated for fixing the elective osteotomies in the metatarsal and phalanges of the foot only. Examples include:

Weil osteotomy
Lesser metatarsal osteotomies

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X 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 K991477

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