4/29/99

NEWDEAL SA • 31 RUE DE LA CONVENTION
PARC D'ACTIVITÉS GARIGLIANO
38200 VIENNE • FRANCE
TEL : (33) 04 74 78 15 15
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K990622

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

DATE OF PREPARATION OF THIS SUMMARY: February 17, 1999

D. PROPRIETARY (TRADE) NAME: **BOLD® SCREW**

E. COMMON NAME: Bone fixation screw
Cannulated compression screw

F. CLASSIFICATION NAME AND REFERENCE

Smooth or threaded metallic bone fixation fastener (21 CFR, Section 888.3040)

000009

D. PROPOSED REGULATORY CLASS: Class II
E. DEVICE PRODUCT CODE: 87HWC
F. PANEL CODE: 87OR

DESCRIPTION OF DEVICE:

The **BOLD® SCREW** is a cannulated screw made of a Titanium alloy. Its design includes a non-threaded shaft and a self-tapping screw tip. Screws come in lengths of 10-34 mm.

INTENDED USE:

The **BOLD® SCREW** is intended to be implanted for fixation of bone fractures or for bone reconstructions.

INDICATIONS FOR USE:

The **BOLD® SCREW** is indicated for fixing the elective osteotomies of the mid-foot bones and the metatarsal and phalanges of the foot only. Examples include:

- Mono or Bi-cortical osteotomies in the forefoot
- Distal or proximal metatarsal osteotomies
- Weil osteotomy
- Fusion of the first metatarsophalangeal joint and interphalangeal joint.
- Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, ...etc.)
- Akin type osteotomy
- Arthrodesis base first metatarsal cuneiform joint to reposition and stabilize metatarsus varus primus

PREDICATE DEVICE:

The **BOLD® SCREW** is substantially equivalent to the Scarf Thread-head Screw (DePuy) (K931155) and the Herbert-Whipple Bone Screw (Zimmer) (K792022)

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Both the **BOLD® SCREW**, the Scarf Thread-head Screw and the Herbert-Whipple Bone Screw have the same intended use and all are indicated for fixing small fractures or osteotomies. All are made from Titanium alloys. The **BOLD® SCREW**, the Herbert-Whipple and the Scarf Thread-head Screw have a non-threaded segment. The thread pitch of the Scarf screw differs slightly while the **BOLD® SCREW** has a double pitch at the tip of the screw compared to the head. Both have a thread head and a hexagonal socket. The Scarf Thread-head Screw, the **BOLD® SCREW** and the Herbert-Whipple screw are all cannulated and are topped with a hexagonal socket.

SUMMARY OF STUDIES:

Rupture torque of the **BOLD® SCREW** was compared with requirements of the French Standard N° NF-F-90-414 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

APR 29 1999

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

Re: K990622
Trade Name: Bold® Screw
Regulatory Class: II
Product Code: HWC
Dated: February 17, 1999
Received: February 25, 1999

Dear Dr. Estrin:

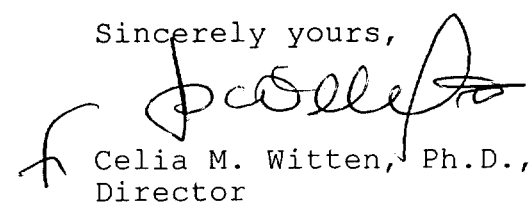
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

510(k) Number (if known): **K990622**

Device Name: **BOLD® SCREW**

Indications for Use:

The **BOLD® SCREW** is indicated for fixing the elective osteotomies of the mid-foot bones and the metatarsal and phalanges of the foot only. Examples include:

- Mono or Bi-cortical osteotomies in the forefoot
- Distal or proximal metatarsal osteotomies
- Weil osteotomy
- Fusion of the first metatarsophalangeal joint and interphalangeal joint.
- Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, ...etc.)
- Akin type osteotomy
- Arthrodesis base first metatarsal cuneiform joint to reposition and stabilize metatarsus varus primus

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

X

Prescription Use 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 K990622 000008