K993910

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newdeal
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PARC D'ACTIVITÉS GARIGLIANO
38200 VIENNE • FRANCE
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FEB 1 2000

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: 9615741

C. OFFICIAL CONTACT PERSON

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

Tel. : (301) 519-1098
Fax : (301)519-1389

D. DATE OF PREPARATION OF THIS SUMMARY: November 15, 1999

E. PROPRIETARY (TRADE) NAME: **TAC'pin®**

F. COMMON NAME: Bone fixation wire
self tapping threaded wire

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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: 87JDW

J. PANEL CODE: 87 OR

K. DESCRIPTION OF DEVICE: The **TAC'pin®** is a self tapping wire. One part is fixed on a standard surgical power tool equipment and when the threaded wire is introduced and positioned as required, the surgeon has to cut the wire at the bone surface. The lengths of threads available are the following : 15 – 20 – 25 mm.

L. INTENDED USE: The **TAC'pin®** is intended to be implanted for fixation of bone fractures or for bone reconstructions.

M. INDICATIONS FOR USE: The **TAC'pin®** is indicated for synthesis of small bones fragments, in the foot only. Examples include:

-Akin type osteotomy
-first MP Arthrodesis
-phalangeal arthrodesis
-small bones osteosynthesis requiring compression.

N. PREDICATE DEVICE The **TAC'pin®** is substantially equivalent to the Threaded fixation pin manufactured by Sgarlato laboratories (K982931), and the Kirschner wires and Steinmann pins manufactured by Syntec-Taichung Medical Instruments (K983121).

O. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Both the TAC'pin®, the Sgarlato threaded fixation pin, and the Kirschner wires and Steinmann pins from Syntec-Taichung Medical are intended to be implanted for fixation of small bone fragments.
Both the TAC'pin® and the Sgarlato threaded fixation pin are made from the same titanium alloy, whereas the Kirschner wires and Steinmann pins from Syntec-Taichung Medical are made from stainless steel. This difference has no significant consequences on the safety or effectiveness of the product. The TAC'pin®, the Sgarlato Threaded fixation pin, and the Kirschner wires and Steinmann pins manufactured by Syntec-Taichung Medical Instruments are all threaded pins with comparable ranges of sizes and diameters.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2000

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

Re: K993910
Trade Name: TAC' pin®
Regulatory Class: II
Product Code: JDW
Dated: November 15, 1999
Received: November 17, 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.

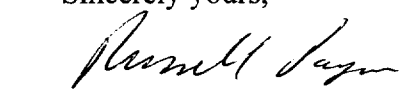
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K993910

510(k) Number (if known):

Device Name: **TAC' pin ®**

Indications for Use:

The **TAC'pin®** is indicated for synthesis of small bones fragments, in the foot only. Examples include:

-Akin type osteotomy
-first MP Arthrodesis
-phalangeal arthrodesis
-small bones osteosynthesis requiring compression.

(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)

Russell Payne Sr

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993910