K993762

1 of 2

FEB 4 2000

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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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: October 18, 1999

E. PROPRIETARY (TRADE) NAME: **I.CO.S® Screw**

F. COMMON NAME: Bone fixation screw, Cannulated compression screw

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: 87 OR Orthopedic

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K. DESCRIPTION OF DEVICE:

The **I.CO.S® Screw** is a cannulated compression screw with non-threaded shaft, allowing optimal compression. The head of this screw can be screwed and translated along the body in order to increase the compression controlled by the surgeon. It also has a self-tapping screw tip. It comes in diameters from 4.0 mm to 6.5 mm and in length from 26 to 90. The **I.CO.S® Screw** is a cannulated compression screw made of titanium alloy. Its design includes a non-theaded shaft, allowing optimal compression. The head of this screw can be screwed and translated along the body in order to increase the compression controlled by the surgeon. It also has a self-tapping screw tip.

L. INDICATIONS FOR USE:

The **I.CO.S® Screw** is indicated for fixing the elective osteotomies of the forefoot and/or mid foot bones and for fractures fixation in the forefoot and/or mid foot and /or hindfoot, including:

*naviculo-cunéiform arthrodesis
*lapidus arthrodesis
*talus osteochondritis
*ankle arthrodesis
*arthrodesis, osteotomies or fractures fixation in the forefoot and/or midfoot and/or the hindfoot.

M. PREDICATE DEVICE:

The **I.CO.S® Screw** is substantially equivalent in design, composition and function to other orthopedics screws manufactured and approved for market:

Orthopeadic Biosystem Ltd.:	K963420
AAP Implants Inc.:	K990776
Synthes:	K962823

N. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Both the **I.CO.S® Screw** , the Self-drilling Facet Screw from Orthopaedic Biosystems Ltd, Synthes sterile 3.0mm Cannulated screw and threaded washer, and the cannulated screw from Aap implants Inc have the same intended use and all are indicated for fixing fractures or osteotomies.

O. SUMMARY OF STUDIES:

The **I.CO.S® Screw** meet the ASTM standards (ASTM F136) for the material and design for medical application. The bone screws are of the same thread configuration and length as offered by **Orthopeadic Biosystem Ltd, Aap Implants Inc, Synthes** and many other orthopaedic companies. The minor and major diameters as well as the head size are comparable. Rupture torque of the I.CO.S® Screw was compared with requirements of the French Standard N° NF-S –90414 and found to have a resistance 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

FEB 4 2000

Mr. Eric Fourcault
President
NewDeal SA
c/o Estrin Consulting Group, Incorporated
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K993762
Trade Name: I.CO.S. Screw
Regulatory Class: II
Product Code: HWC
Dated: November 7, 1999
Received: November 8, 1999

Dear Mr. Fourcault:

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,

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

Enclosure

510(k) Number (if known): K 9 9 3 7 6 2

Device Name: **I.CO.S.®** **SCREW**

Indications for Use:

The **ICOS® SCREW** is indicated for fixing the elective osteotomies of the forefoot and/or mid foot bones and for fractures fixation in the forefoot and/or mid foot and /or hindfoot, including:

*naviculo-cunéiform arthrodesis
*lapidus arthrodesis
*talus osteochondritis
*ankle arthrodesis
*arthrodesis, osteotomies or fractures fixation in the forefoot and/or midfoot and/or the hindfoot.

NBO for 5TD
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993762

(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)

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