

JUN 3 1999

Disc-O-Tech Medical Technologies, Ltd.
Fixion Intramedullary Nailing System 510K

K 99 0717

7.1

510(K) Summary

Disc-O-Tech Medical Technologies Fixion Intramedullary Nailing System

Company Name

Disc-O-Tech Medical Technologies, Inc.
3 Hasadnaot St. Herzlia
Israel, 46728

Submitter's Name and Contact Person

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Date Prepared

February, 1999.

Trade/Proprietary Name

FixionTM Intramedullary Nailing System

Classification Name

Intramedullary Fixation Rod
21 C.F.R. § 888.3020
Class II

Predicate Devices

- CINTOR Orthopedic Div's Aginsky Nail (K803106)
- HOWMEDICA's Seidel Humeral Locking Nail (K883882, K924004, K925544, K931256)
- SYNTHES's AO Universal Tibial and Femoral Nails (K914453, and K914371)
- SYNTHES's AO Unreamed Humeral (UHN) Tibial (TNN) and Femoral (UFN) Nails (K933518, K932330, and K923580, respectively).

Performance Standards

No performance standards applicable to Intramedullary Nails have been established by the FDA. However, the following standards were used:

- Stainless steel 316L which is used to manufacture the Fixion™ Intramedullary Nailing System meets the requirements of ASTM F138 - Standard Specification for Stainless steel Bar and Wire for Surgical Implants.
- The 4 point bending mechanical testing was performed according to ASTM F1264 - standard for mechanical performance considerations for intramedullary fixation devices.
- The torsional mechanical testing was performed according to ASTM F383 - Standard Practice for Static Bend and Torsion Testing of Intramedullary Rods.

Intended Use

The Fixion™ Intramedullary Nailing System ("Fixion™ Nail") is intended for use in the fixation of long bone fractures, including diaphyseal fractures in the humerus, femur and the tibia. It is indicated for use in shaft fractures 5cm below the surgical neck to 5cm proximal to the distal end of the medullary canal.

System Description

The Fixion™ Intramedullary Nailing System is a single use system that features 3 main components: Nail implant, Driver, and Inflation device.

- The **Nail implant** is an expandable non-slotted stainless steel cylindrical tube, with a conical shaped distal end and a cap protected, female threaded proximal end.
- The **Driver** is a stainless steel cylinder with plastic handle, used for the nail insertion, location and adjustment at the intramedullary canal. In addition, it serves as a delivery system for the inflation liquid.
The Driver has a male threaded end to be connected to the Nail implant proximal end. A quick connector is located on the Driver to be connected to the Inflation device.
- The **Inflation device** is a single use manual plastic “pump”, filled with sterile inflation liquid, similar to a PTCA inflation pump but with higher pressure. The inflation device outlet pipe end has a female quick connector to be connected to the Driver connector.

Once the nail is positioned within the medullary canal, rotation of the “pump” handle allows for nail diameter increase to its intended diameter under X-ray and controlled pressure.

Substantial Equivalence

The Fixion™ Nail has the same intended use and substantially similar indications for use as the predicates, i.e., fixation of long bone fractures of the humerus, tibia, and femur.

The performance characteristics of the Fixion™ Nail have been tested and approved through a series of in-vitro and animal studies.

The Fixion™ Nail, like the Synthes Universal Tibial and Femoral Nails, is a Stainless Steel 316L canulated design. The cross section of the Fixion™ Nail is circular with reinforcement bars, which was found to be equivalent in mechanical properties to the circular cross section of the predicate devices.

With respect to fixation, the expansion of the Fixion™ Nail results in the attachment of the 4 reinforcement bars to the medullary canal wall, providing equivalent fixation to the distal mechanism of the Seidel Humeral locking nail, in which the nail distal end’s three leaves are expanded and attached to the medullary canal wall.

The expansion of the Fixion nail with saline, which is a non-compressible biocompatible fluid, does not raise any safety concerns.



JUN 2 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Jonathan s. Kahan, Esq.
Hogan & Hartson, L.L.P.
Representing Disc-O-Tech Medical Technologies, Inc.
555 Thirteenth Street, N.W.
Washington, DC 20004

Re: K990717
Trade Name: Fixion™ Intramedullary Nail System
Regulatory Class: II
Product Code: HSB
Dated: February 24, 1999
Received: March 4, 1999

Dear Mr. Kahan:

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.

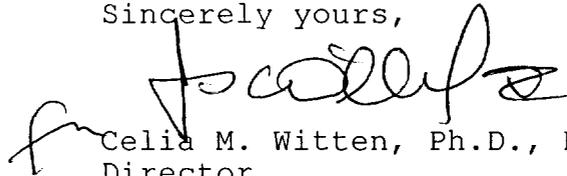
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Jonathan s. Kahan, Esq.

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

INDICATION FOR USE

510(K) Number (if known): k990717

Device Name: Fixion™ Intramedullary Nailing system

Indication for Use: The Fixion™ Intramedullary Nailing system is intended for use in the fixation of long bone fractures, including diaphyseal fractures in the humerus, femur and the tibia. It is indicated for use in shaft fractures 5cm below the surgical neck to 5cm proximal to the distal end of the medullary canal.

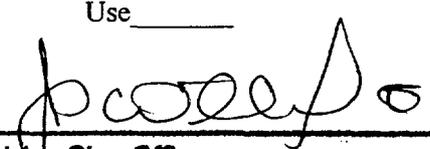
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Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)
Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices

510(k) Number: _____

Prescription Use X
(per 21 CFR 801.109)

OR Over the Counter
Use _____



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number k99071