JUN 1 9 2001

K010901

510(K) Summary
Disc-O-Tech Medical Technologies Fixion™ Intramedullary Nailing System

Company Name

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

Submitter's Name and Contact Person

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Date Prepared

February 2001

Trade/Proprietary Name

Fixion™ Intramedullary Nailing System

Classification Name

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

Predicate Devices

- Fixion™ Intramedullary Nailing System, cleared under 510(k) number K990717, K003212, K003125
- Seidel Humeral Locking Nail cleared under 510(k) number K883882, K924004, K925544, K931256
- Unreamed Humeral Nail cleared under 510(k) number K933518
- Unreamed Femoral Nail cleared under 510(k) number K923580
- Universal Femoral Nail cleared under 510(k) number K914371
- True/Flex Upper Extremity IM Nail cleared under 510(k) number K902264

Performance Standards

The FDA has established no mandatory performance standards applicable to Intramedullary Nails. However, the following standards were adhered to:

- 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™ IMN") 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 consist of the following main components:

1. The **Nail Implant** is an expandable, sealed, stainless steel, cylindrical, ribbed rod without interlocking holes. The proximal end has a one way valve for inflation. The nail is cap protected.
2. The **Insertion Handle** is a device designed to be connected to the nail's proximal end, and used for nail insertion. Its distal end has a locking sleeve to prevent relative rotation between the nail and the handle.
3. The **Inflation Device** is a manual plastic "pump", filled with sterile inflation liquid, similar to a PTCA inflation pump. Rotation of its handle delivers saline into the nail. The pump pressure gauge indicates the inflation pressure. This action causes the nail's expansion and abutment to the bone medullary cavity. The inflation device outlet pipe end has connector to be connected to the insertion handle.

In addition the system consists of a removal kit including a removal adapter, a slide hammer and a slide hammer adapter and a cap driver.

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™ IMN 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™ IMN have been tested and approved through a series of in-vitro, animal studies and clinical studies.

The Fixion™ IMN, like predicate devices, is a Stainless Steel 316LVM canulated design. The cross section of the Fixion™ IMN is circular with reinforcement bars, which is equivalent to the cross section of the predicate device.

With respect to fixation, the expansion of the Fixion™ IMN results in the attachment of the 4 reinforcement bars to the medullary canal wall, providing equivalent fixation to

predicate devices. Both the pressurized version of the Fixion IMN and the predicate version of the Fixion IMN undergo the same plastic deformation once expanded, thus activating the same pressure on the bone. Removal of the pressurized Fixion IMN is identical to the removal of the predicate Fixion IMN – once the pressure in the nail is reduced, the extraction procedure and nail behavior are identical to those observed for the predicate, cleared, Fixion IMN.

The expansion and continued pressurization until removal (if required) of the Fixion™ IMN does not raise any safety concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 9 2001

Disc-O-Tech Medical Technologies, LTD.
c/o Mr. Johnathan S. Kahan, Esq.
555 Thirteenth Street, NW
Washington, DC 20004

Re: K010901
Trade Name: Fixion Intramedullary Nailing System (Fixion IMN) Model B
Regulation Number: 888.3020
Regulatory Class: II
Product Codes: HSB
Dated: March 12, 2001
Received: March 26, 2001

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 control provisions of the Act. The general control 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(K) Number (if known): K010901

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.

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

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 and Neurological Devices

510(k) Number K010901