MAY 23 2002

K021324
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# 510(K) Summary

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

**Company Name**

Disc-O-Tech Medical Technologies, Ltd.
3 Hasadnaot St., Herzelia
Israel, 46728

**Submitter's Name and Contact Person**

Yael Rubin
Disc-O-Tech Medical Technologies, Ltd.
3 Hasadnaot St., Herzelia
Israel, 46728
Tel: +972 9 9511511
Fax: +972 9 9548939

**Date Prepared**

April 2002

**Trade/Proprietary Name**

Fixion™ Intramedullary Nailing System (Fixion IM Nailing System)

**Classification Name**

Intramedullary Fixation Rod
21 CFR § 888.3020
Class II

**Predicate Devices**

1. Fixion Intramedullary Nailing System (K990717, K003212, K003215, K010901) by Disc-O-Tech.
2. Fixion Interlocking Proximal Femoral Intramedullary Nailing System (K010988, K012967) by Disc-O-Tech.

**Performance Standards**

The following standards were used:

1. The Fixion IM Nail is manufactured from 316L stainless steel, which meets the requirements of ASTM F138 - Standard Specification for Stainless Steel Bar and Wire for Surgical Implants.
2. The Fixion IM Nailing System accessories incorporate surgical grade stainless steel (ASTM 899, ASTM F1586) and Celeron (ISO 16061).
3. The Fixion IM Nail is designed to meet the requirements of ASTM F565 – Standard Practice for Care and Handling of Orthopedic Implants and Instruments.

**Intended Use**

The Fixion Intramedullary Nail is intended for use in the fixation of long bone fractures, including diaphyseal fractures in the humerus, tibia and femur. It is indicated for shaft fractures 5cm below the surgical neck, and 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 expansion. The nail is cap protected.
2. The **Insertion Handle** is a device designed to be connected to the nail proximal end, and used for nail insertion. Its distal end has locking "teeth" to prevent relative rotation between the nail and the handle.
3. The **Inflation Device** is a pump, which rotation of its handle delivers saline into the nail. The pump pressure gauge indicates the expansion pressure. This action causes the nail expansion and abutment to the bone medullary cavity.

In addition the system consists of additional accessories including a removal adapter, a slide hammer and a slide hammer adapter and a screwdriver.

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 IM Nailing System is substantially equivalent to the Fixion IM Nailing System cleared for marketing under 510(k) K990717, K003212, K003215, K010901, and to the Fixion Interlocking Proximal Femoral Intramedullary Nailing System cleared for marketing under 510(k) K010988, K012967.

The modified Fixion IM Nail has the following similarities to that which previously received 510(k) concurrence:

- Have the same intended use
- Have the same operating principles
- The Nail and the Instrumentation Set incorporate the same design
- The Nail and the Instrumentation Set incorporate the same materials
- The Nail and the Instrumentation Set have the same packaging and sterilization, using the same materials and processes.

The components of the Insertion Kit, which are now supplied separately, are either identical or similar in design, materials, packaging and sterilization to other components of the Fixion IL and PF Nailing Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2002

Mr. Yael Rubin
Director of Regulatory Affairs
Disco-O-Tech Medical Technologies, Inc.
3 Hasadnaot St.
Herzelia, Israel 46728

Re: K021324
Trade/Device Name: Fixion™ Intramedullary Nailing System (Fixion™ IM Nail)
Regulation Number: 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: April 24, 2002
Received: April 26, 2002

Dear Mr. Rubin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia 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):** K021324

**Device Name:** Fixion™ Intramedullary Nailing System (Fixion™ IM Nail)

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

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021324

(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)