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K030972
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510(K) Summary

Disc-O-Tech Medical Technologies Ltd.
Fixion® Unipolar Modular Hemi-Hip System (Fixion® MH) -
10/16 mm stem body; 12 mm stem neck; 316L stainless steel head ball.

Company Name and Address

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

Submitter's Name and Contact Person

Hila Wachsler-Avrahami
Disc-O-Tech Medical Technologies Ltd.
3 Hasadnaot St.
Herzelia 46728
Israel
Tel.: + 972 9 9511511
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Date Prepared

March 26, 2003

Trade/Proprietary Name

Fixion® Unipolar Modular Hemi-Hip System (Fixion® MH)

Classification Name

Prosthesis, Hip, Hemi-, Femoral, Metal
21 CFR § 888.3360
Class II

Predicate Devices

1. Fixion® Unipolar Modular Hemi-Hip System (K014072) by Disc-O-Tech.
2. Fixion Interlocking Proximal Femur Intramedullary Nailing System (K010988, K012967) by Disc-O-Tech.

Performance Standards

The following standards were used:

1. ISO 7206-1 (1995): Implants for Surgery - Partial and Total Hip Joint Prostheses - Part 1: Classification and Description of Dimensions.
2. ISO 7206-4 (Draft, 1999): Implants for Surgery - Partial and Total Hip Joint Prostheses - Part 4: Determination of Endurance Properties of Stemmed Femoral Components.
3. ISO 7206-8 (1995): Implants for Surgery - Partial and Total Hip Joint Prostheses - Part 8: Endurance Performance of Stemmed Femoral Components with Application of Torsion.
4. Guidance Document for Femoral Stem Prostheses (Draft), ORDB/DGRD/CDRH/FDA, August 1, 1995.
5. Guidance Document for Testing Non-Articulating, "Mechanically Locked", Modular Implant Components (Draft), ORDB/DGRD/CDRH/FDA, May 1, 1995.
6. ASTM F138-2000: Standard Specification for Stainless Steel Bar and Wire for Surgical Implants.
7. ASTM F565-2000: Standard Practice for Care and Handling of Orthopedic Implants and Instruments.

Intended Use

The Fixion® MH System is intended for cemented or non-cemented use as a hemi-hip replacement. It is indicated for use in cases of:

- Femoral head and/or neck fractures or non-unions;
- Aseptic necrosis of the femoral head and/or neck;
- Osteo-, Rheumatoid-, and/or Post-traumatic arthritis of the hip, with minimal acetabular involvement.

System Description

The Fixion® MH System is a modular hemi-hip system, which consist of the following main components:

1. **Implants** (stainless steel), including the stem and head ball. The stem is the femoral diaphyseal component. It consists of an expandable stem body and a neck part. The unipolar head ball is the prosthesis hip component that articulates within the acetabulum.
2. The **Instrumentation Set** is a set of accessories, including pre-operative tools, femoral canal preparation tools and accessories such as the stem insertion handle, inflation adapter, screwdriver for stem cap insertion and devices for implant removal.
3. The **Inflation Device** is a pump, which rotation of its handle delivers saline into the stem. This action causes the expansion of the stem and its abutment to the bone medullary cavity. The pump pressure gauge indicates the inflation pressure.

Substantial Equivalence

The Fixion® MH 10/16 stem (with a neck width of 12 mm) and the Fixion® MH 316L stainless steel head balls are substantially equivalent to the cleared stem and head balls of the Fixion® MH System (K014072):

- ❖ They have the same intended use and indications for use;
- ❖ They incorporate the same basic design;
- ❖ They have the same operating principles;
- ❖ They have the same fixation method;
- ❖ They are packed and sterilized using the same materials and processes.

The added components are made of the same materials as the cleared Fixion® MH stem.

In addition, the dimensions of the added Fixion® MH stem body, neck and head balls are within the range of sizes of other cleared, marketed systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2003

Ms. Hila Wachsler-Avrahami
Regulatory Affairs
Disc-O-Tech Medical Technologies Ltd.
3 Hasadnaot Street
Herzelia
Israel 46728

Re: K030972
Trade/Device Name: Fixion® Unipolar Modular Hemi-Hip System (Fixion® MH)
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWL
Dated: April 29, 2003
Received: May 1, 2003

Dear Ms. Wachsler-Avrahami:

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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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 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): K030972

Device Name: Fixion® Unipolar Modular Hemi-Hip System (Fixion® MH)

Indication for Use: The Fixion® MH System intended for cemented or non-cemented use as a hemi-hip replacement. It is indicated for use in cases of:

- Femoral head and/or neck fractures or non-unions;
- Aseptic necrosis of the femoral head and/or neck;
- Osteo-, Rheumatoid-, and/or Post-traumatic arthritis of the hip, with minimal acetabular involvement.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over the Counter Use _____
(per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030972