MAR 2 6 2004

K032730

510(K) Summary

Disc-O-Tech Medical Technologies Ltd.

Fixion® Hip System

Company Name

Disc-O-Tech Medical Technologies Ltd.

3 Hasadnaot St.

Herzliya 46728, Israel

Submitter's Name and Contact Person

Hila Wachsler-Avrahami

Disc-O-Tech Medical Technologies, Ltd.

3 Hasadnaot St.

Herzliya 46728, Israel

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Date Prepared

August 2003

Trade/Proprietary Name

Fixion® Hip System

Classification

Class II

Predicate Devices

- Fixion® Unipolar Modular Hemi-Hip System (Fixion® MH, K014072, K030972) by Disc-O-Tech Medical Technologies Ltd.
- U1 Hip System (K994078) by United Orthopedic Corporation.
- Elite® Modular Hip System (K871867) by Depuy Orthopeadics.
- S-ROM® Total Hip System (K851422, K913231, K954935, K961939) by Depuy Orthopeadics.
- Link® MP® Hip System (K955296) by Link America Inc.
- Fixion® Interlocking Proximal Femoral Intramedullary Nailing System (Fixion® PF, K010988, K012967, K023437) by Disc-O-Tech Medical Technologies Ltd.

Performance Standards

The following standards were referred:

- ISO 7206-1 (Draft, 1995): Implants for Surgery – Partial and Total Hip Joint Prostheses – Part 1: Classification and Description of Dimensions.
- ISO 7206-4 (Draft, 1999): Implants for Surgery – Partial and Total Hip Joint Prostheses – Part 4: Determination of Endurance Properties of Stemmed Femoral Components.
- 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.
- Guidance Document for Femoral Stem Prostheses (Draft), ORDB/DGRD/CDRH/FDA, August 1, 1995.
- Guidance Document for Testing Non-Articulating, "Mechanically Locked", Modular Implant Components (Draft), ORDB/DGRD/CDRH/FDA, May 1, 1995.
- ASTM F 138-2000: Standard Specification for Stainless Steel Bar and Wire for Surgical Implants.

- ASTM F 565-2000: Standard Practice for Care and Handling of Orthopedic Implants and Instruments.
- ASTM F 1586-95: Wrought Nitrogen Strengthened - 21 Chromium - 10 Nickel - 3 Manganese - 2.5. Molybdenum Stainless Steel Bar for Surgical Implants.
- ISO 5832-1 (1997): Implants for Surgery - Metallic Materials - Part 1: Wrought High Nitrogen Stainless Steel.
- ISO 5832-9 (1995): Implants for Surgery - Metallic Materials - Part 9: Wrought High Nitrogen Stainless Steel.
- BS EN 12563: 1999 - Non-active surgical implant - Joint replacement implants - Specific requirements for hip joint replacement implants.

Intended Use

The Fixion® Hip System is intended for use as a hemi-hip or total hip replacement. The Fixion® Hip System is indicated as a unipolar hemi-hip replacement 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.

The Fixion® Hip System is indicated as a total hip replacement in cases of:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

The Fixion® Hip Stem is intended for cemented or non-cemented use.

System Description

The Fixion® Hip System is composed of an implant, inflation device (pump) and an instrumentation set.

- Implant - comprises femoral stem and head ball, and – for total hip replacement – acetabular cup and liner and cancellous bone screws, as detailed below:
  - A stainless steel ***Stem***, including stem body and neck, which is inserted into the femoral medullary canal and expanded following insertion.
  - A ***Head Ball***, assembled on the stem neck and articulates within the acetabulum (in hemi-hip replacement) or acetabular cup and liner (in total hip replacement). A unipolar stainless steel head (for hemi- hip replacement), and a cobalt chromium head (for total hip replacement) are available.
  - A porous coated, cobalt chromium ***Acetabular Cup***, inserted and fixated within the acetabulum.
  - A UHMWPE ***Acetabular Cup Liner***, which is seated inside the acetabular cup.
  - Cobalt chromium ***Cancellous Bone Screws***, intended to fixate the acetabular cup to the acetabulum, in cases additional stabilization of the cup is required.
- Instrumentation Set – a set of accessories to be used with the Fixion® Hip implants.
- Inflation Device (Pump) – a manual pump used to expand the Fixion® stem.

Substantial Equivalence

The Fixion® Hip System intended use, design, materials, technological characteristics and principles of operation are substantially equivalent to those of Disc-O-Tech's Fixion® Unipolar Modular Hemi-Hip System (K014072, K030972), Fixion® Interlocking PF Intramedullary Nailing System (K010988, K012967,

K023437), United Orthopedic Corporation' U1 Hip System (K994078), Depuy Orthopaedics' Elite® Modular Hip System (K871867) and S-ROM® Total Hip System (K851422, K913231, K954935, K961939 and others), and the Link America Inc.' Link® MP® Hip System (K955296).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2004

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

Re: K032730
Trade/Device Name: Fixion® Hip System
Regulation Numbers: 21 CFR 888.3350; 21 CFR 888.3358; 21 CFR 888.3360
Regulation Names: Hip joint metal/polymer semi-constrained cemented prosthesis; Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis; Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.
Regulatory Class: II
Product Codes: JDI, LPH, MBL, KWL, JDG, LWJ
Dated: December 25, 2003
Received: December 29, 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" (21CFR 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 Mark N. Melkerson

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

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

510(K) Number (if known): K032730

510(k) Number K032730

Device Name: Fixion® Hip System

Indication for Use:

The Fixion® Hip System is intended for use as a hemi-hip or total hip replacement.

The Fixion® Hip System is indicated as a unipolar hemi-hip replacement 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.

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- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

The Fixion® Hip Stem is intended for cemented or non-cemented use.

Prescription Use ____√____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)