NOV 1 8 2005

K051826

510(k) SUMMARY

Waldemar Link GmbH & Co. KG's BetaCone™ Hip Prosthesis System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Waldemar Link GmbH & Co. KG
Barkhausenweg 10
D-22339 Hamburg
Germany
Telephone: 49 (0)40 5 39 95-0
Fax: 49 (0)40 5 38 69 29

Contact Person: Peter Keller

Date Prepared: July 5, 2005

Name of Device and Name/Address of Sponsor

BetaCone™ Hip Prosthesis System

Waldemar Link GmbH & Co. KG
Barkhausenweg 10
D-22339 Hamburg
Germany

Common or Usual Name

Femoral Hip Stem

Classification Name

Hip joint metal/polymer semi-constrained cemented prosthesis, 21 C.F.R. § 888.3350, JDI;
Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis, 21 C.F.R. § 888.3360, LWJ.

Predicate Devices

Encore Orthopaedics' SL-Plus and SLR-Plus Stems (Encore) (K930963);
Centerpulse's CLS Spotorno Stems (CLS) (K042249, K010839);
Zimmer's Alloclassic Femoral Stems (Alloclassic) (K033664, K030373).

Intended Use / Indications for Use

The BetaCone is intended for non-cemented use to replace the anatomy of the femur in cases of total hip replacement. It is indicated in the treatment of the following:

- Patient conditions of noninflammatory degenerative joint disease, *e.g.*, avascular necrosis and osteoarthritis; and inflammatory joint disease, *e.g.*, rheumatoid arthritis;
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists; and
- Revision of a previously failed hip arthroplasty.

Technological Characteristics and Substantial Equivalence

Both the BetaCone and the predicate Encore, CLS, and Alloclassic Hip Stems use titanium alloy straight, tapered stems to replace the femur in hip replacement procedures. The BetaCone is fabricated from Ti-6Al-4V titanium alloy. BetaCone stems are available in 9 standard and 9 XL sizes, with lengths ranging from 135 to 175 mm. The BetaCone stem has a rectangular cross-section slightly rounded in both planes. BetaCone XL neck lengths are 5 mm longer than standard stem neck lengths. The BetaCone neck angle is 126°.

A 12/14 taper connects with Link's prosthesis heads using the same size taper. The BetaCone is compatible with Link standard acetabular cups.

The BetaCone stem is designed for uncemented, press-fit fixation. A proximal trochanter fin supports proximal press-fit fixation.

The BetaCone is substantially equivalent to the other currently marketed femoral hip stems which are referenced above. The BetaCone and its predicate devices have the same intended use and indications for use; all are titanium alloy, straight, tapered stems available in a similar range of sizes and employing the same essential design geometry. Thus, the BetaCone raises no new issues of safety or effectiveness.

Performance Data – Bench Testing

The BetaCone prosthesis was subjected to dynamic fatigue testing in accordance with ISO 7206-4: 2002, using an 80mm potting level. Five samples of the same sized, worst case stem were tested. No prosthesis tested at a maximum load of 2.3kN failed up to 5 million cycles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 8 2005

Waldemar Link GmbH & Co. KG
c/o Janice M. Hogan, Partner
Hogan & Hartson L.L.P.
1835 Market Street, 28th Floor
Philadelphia, Pennsylvania 19103

Re: K051826
Trade/Device Name: BetaCone™ Hip Prosthesis System
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Regulatory Class: II
Product Code: LWJ, JDI
Dated: November 2, 2005
Received: November 2, 2005

Dear Ms. Hogan:

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.

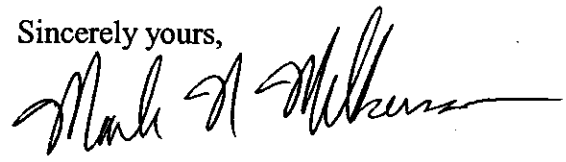
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K051826

Device Name: BetaCone™ Hip Prosthesis System

Indications for Use:

The BetaCone is intended for non-cemented use to replace the anatomy of the femur in cases of total hip replacement. It is indicated in the treatment of the following:

- Patient conditions of noninflammatory degenerative joint disease, *e.g.*, avascular necrosis and osteoarthritis; and inflammatory joint disease, *e.g.*, rheumatoid arthritis;
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists; and
- Revision of a previously failed hip arthroplasty.

Mark A Miller

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

510(k) Number K051826

Prescription Use √ AND/OR Over-The-Counter Use ____
(Per 21 C.F.R. 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)