K994366

MAR 1 6 2000

510(k) Summary

Device: TMZF® Press Fit HA Stem and TMZF® Press Fit Plus HA Stem

The TMZF® Press Fit HA Stem and TMZF® Press Fit Plus HA Stem are neutral, press fit femoral stems consisting of a variety of lengths. The devices are available in two neck angle options for each corresponding body geometry. These femoral stems contain a symmetric wedge with a groove running along each stem's axis distally up to the mid stem region.

These stems are intended for the reconstruction of the head and neck of the femoral joint. The device is intended for primary reconstruction of the proximal femur or revision of a previous total hip arthroplasty. These stems can be used with any currently available Howmedica Osteonics acetabular components and V40™ Femoral Heads that can be mated with a 5° 40' BG taper.

The TMZF® Press Fit HA Stem and TMZF® Press Fit Plus HA Stem will be fabricated from TMZF® alloy. The stems are coated with a CP Titanium plasma spray coating and Pure-Fix™ HA.

The substantial equivalence of the TMZF® Press Fit HA Stem and TMZF® Press Fit Plus HA Stem is based upon equivalence in intended use, materials, design, and operational principles to the Meridian® Titanium Femoral Stem (K972228); the Howmedica® Asymmetric Stem Femoral Component (K955871); the Osteonics® Omnifit® AD-HA Hip Stem Series (K941366); and the Biomet® Taperloc™ Hip System (K921301).

Testing indicates that the addition of the HA coating over plasma spray has no detectable effect on the stem fatigue strength.

For information contact: Ms. Nancy J. Rieder
Rutherford Regulatory Affairs
Howmedica Osteonics Corp.
359 Veterans Boulevard
Rutherford, NJ 07070-2584
Phone: (201) 507-7956
Fax: (201) 507-6870
E-mail: NRieder@HowOst.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 6 2000

Ms. Nancy J. Rieder
Rutherford Regulatory Affairs
Stryker Howmedica Osteonics Corporation
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K994366
Trade Name: TMZF® Press Fit HA Stem and TMZF® Press Fit Plus HA Stem
Regulatory Class: II
Product Code: MEH
Dated: December 23, 1999
Received: December 27, 1999

Dear Ms. Rieder:

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.

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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,

Neal R.P. Ogden for CMW

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

Enclosure

Indications for Use

510(k) Number (if known): K994366

Device Name: TMZF® Press Fit HA Stem and TMZF® Press Fit Plus HA Stem

Indications for Use:

The TMZF® Press Fit HA Stem and TMZF® Press Fit Plus HA Stem are indicated for cementless primary hip surgery in cases of non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis, rheumatoid arthritis, and correction of functional deformity. Additionally, these femoral stems can be used in the treatment of nonunion, and femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques. These stems are also indicated for use in revision procedures where other treatments or devices have failed.

NMB for cmw

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994366

(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)

(Optional Format 1-2-96)