Special 510(k) Summary

Line Extension to the Accolade™ Hip System – Accolade™ TMZF® PLUS HA 127° Size 0 Hip Stem

Proprietary Name:	Accolade™ TMZF® Plus HA 127° Size 0 Hip Stem
Common Name:	Artificial Hip Component
Classification Name and Reference:	Hip joint, metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR §888.3353
Proposed Regulatory Class:	Class II
Device Product Code:	87 MEH
Predicate Proprietary Name:	Accolade™ TMZF® Plus HA Hip Stem
Predicate Regulatory Class:	Class II
Predicate Product Code:	87 MEH
For Information contact:	Debra Bing Howmedica Osteonics Corp. 59 Route 17 Allendale, New Jersey 07401-1677 Phone: (201) 831-5413 Fax: (201) 831-6038

Description/Technological Comparison

The existing Accolade™ TMZF® HA Hip System features femoral stems in neutral, press-fit versions consisting of a variety of lengths and two neck angles, 132° and 127°. The subject Accolade™ TMZF® Plus HA 127° Size 0 Hip Stem is an addition to the existing hip stems. It features a 127° neck angle and will be offered in an additional size (size 0). The Accolade™ TMZF® Plus HA Size 0 Hip Stem is intended for smaller size patient populations. The subject

hip stem, like the predicate hip stems, is manufactured using TMZF® alloy and is also coated with a CP Titanium plasma spray coating and PureFix™ HA.

Intended Use

The subject hip stem is a single-use device intended for use in total hip replacement. It is intended for the reconstruction of the head and neck of the femoral joint. This hip stem is intended for primary reconstruction of the proximal femur or revision total hip arthroplasty. This device is intended for use with any currently available Howmedica Osteonics acetabular component and V40™ femoral heads that can be mated with a TMZF 5° 40' BG trunnion.

Indications:

- Cementless primary hip surgery in cases of non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis, rheumatoid arthritis, and correction of functional deformity.
- Treatment of nonunion, and femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
- Revision procedures where other treatments or devices have failed.

Testing Summary

Testing was employed to evaluate the Accolade™ TMZF® Plus HA Size 0 Hip Stem component. Testing demonstrated that this hip stem component successfully maintains the proper strength requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 9 2002

Mr. William J. Cymbaluk
Vice President
Quality Assurance, Regulatory Affairs and Clinical Research
Stryker Howmedica Osteonics
59 Route 17 South
Allendale, N.J. 07401

Re: K023102
Trade/Device Name: Accolade™ TMZF® Plus HA 127° Size 0 Hip Sem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/ceramic/Polymer Semi-Constrained Cemented or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MEH
Dated: September 17, 2002
Received: September 18, 2002

Dear Mr. Cymbaluk:

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,

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

510(k) Number (if known): K023102

Device Name: Line Extension to the Accolade™ Hip System – Accolade™ TMZF® Plus 127° Size 0 Hip Stem

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes OR Over-The-Counter Use NO (Per 21 CFR 801.109)
(Optional Format 1-2-96)

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

510(k) Number K023102