K052542

SEP 27 2005

stryker Howmedica OSTEONICS

325 Corporate Drive
Mahwah, NJ USA 07430

510(k) Summary of Safety and Effectiveness for the Accolade® RPS Femoral Stem

Proprietary Name:	Accolade® RPS Femoral Stem
Common Name:	Total Hip Joint Replacement Prosthesis
Classification Name and Reference	Hip joint, metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prostheses, 21 CFR §888.3353
Regulatory Class:	Class II
Device Product Code:	87 MEH - prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate, 87 LZO - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented
For Information contact:	Tiffani Rogers Regulatory Affairs Specialist Stryker Orthopaedics 325 Corporate Drive Mahwah, New Jersey 07430 Phone: (201) 831-5412 Fax: (201) 831-6038 E-Mail: Tiffani.Rogers@stryker.com
Date Summary Prepared:	September 13, 2005

Device Description

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® RPS Hip Stem is a modification to the existing hip stems. It features a reduction in the area of Commercially Pure Titanium (CP-Ti) plasma spray and PureFix™ HA coatings on

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proximal body of the stem. The subject hip stem, like the predicate hip stems, is manufactured using TMZF® alloy.

Intended Use:

The subject hip stem is a single-use, sterile 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.

Substantial Equivalence:

The determination of the substantial equivalence of the Accolade® RPS hip stem is based on its similarities in intended use, design and sterilization to the Accolade® TMZF® femoral stem (K994366, cleared March 16, 2000). Predicate device information is located in **Appendix E.**

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2005

Ms. Tiffani D. Rogers
Regulatory Affairs Specialist
Stryker Howmedica Osteonics Corporation
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K052542
Trade/Device Name: Accolade® RPS Hip Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO, MEH
Dated: September 14, 2005
Received: September 15, 2005

Dear Ms. Rogers:

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

510(k) Number (if known): _____

Device Name: Accolade® RPS Hip Stem

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.

Prescription Use ___X___ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K052542