K051223

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325 Corporate Drive
Mahwah, NJ USA 07430

510(k) Summary of Safety and Effectiveness for the HIPSTAR Femoral Stem

Proprietary Name:	HIPSTAR 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 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis 21 CFR §888.3360 Hip joint metal/polymer constrained cemented or uncemented prosthesis 21 CFR §888.3310
Regulatory Class:	Class II
Device Product Code:	87 LZO - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented 87 LWJ - prosthesis, hip, semi-constrained, metal/polymer, uncemented 87 MEH - prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate 87 KWL - prosthesis, hip, hemi-, femoral, metal 87 KWZ - prosthesis, hip, constrained, cemented or uncemented, metal/polymer

For Information contact:

Tiffani Rogers
Regulatory Affairs Specialist
Stryker Orthopaedics
325 Corporate Drive
Mahwah, New Jersey 07432
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Date Summary Prepared: May 5, 2006

Device Description

The Hipstar® Femoral Stem is a straight hip stem manufactured from titanium alloy, TMZF™. The Hipstar® hip features a proximal, lateral flare for rotational stability, with a narrow distal stem for implant stability. The body of the stem, with the exception of the trunnion, neck and distal tip, is iron grit blasted for increased bone to implant interface.

Intended Use:

The Hipstar® hip stem is a single-use device intended for cementless fixation within the prepared femoral canal.

Indications

The Hipstar® Hip Stem is intended for use in total and hemi hip arthroplasty for the following indications:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- rheumatoid arthritis (excepting the Osteolock™ HA Acetabular Cup and Peri-Apatite coated prostheses);
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and,
- treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

When mated with a constrained acetabular liner the Hipstar® Hip Stem is indicated for use in primary and revision total hip arthroplasty for patients at high risk of hip dislocation due to a history of prior dislocations, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

Substantial Equivalence:

The determination of the substantial equivalence of the HIPSTAR® hip stem is based on its similarities in intended use, design and sterilization to Zimmer's Alloclassic™ Zweymueller™ SL/SLL femoral hip stem (K030373, cleared March 06, 2003).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 2006

Stryker® Orthopaedics
% Ms. Tiffani Rogers
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07432

Re: K051223
Trade/Device Name: Hipstar® Hip Stem
Regulation Number: 21 CFR 878.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis
Regulatory Class: II
Product Code: LZO
Dated: March 31, 2006
Received: April 3, 2006

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/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

K051223

510(k) Number (if known): _____

Device Name: Hipstar® Hip Stem

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The Hipstar® Hip Stem is intended for cementless use only.

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 K051223