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510(k) Summary of Safety and Effectiveness for the JAVELIN SHOULDER

Proprietary Name:	Javelin Shoulder
Common Name:	Artificial Shoulder Humeral Components
Classification Name and Reference	Shoulder joint metal/polymer semi-constrained cemented prostheses, 21 CFR §888.3660 or Shoulder joint humeral (hemi-shoulder) metallic uncemented prostheses, 21 CFR §888.3690
Regulatory Class:	Class II for §888.3660 Class II for §888.3690
Device Product Code:	87 KWS: prosthesis, shoulder, semi-constrained, metal/polymer cemented 87 HSD: prosthesis, shoulder, hemi-, humeral, metallic uncemented
For Information contact:	Karen Ariemma Regulatory Affairs Specialist Stryker Orthopaedics 325 Corporate Drive Mahwah, New Jersey 07430 Phone: (201) 831-5718 Fax: (201) 831-6038 E-Mail: Karen.ariemma@stryker.com
Date Summary Prepared:	January 5, 2005

Device Description

The Javelin Shoulder is a fully anatomic design with an articulating humeral head that will allow it to be placed in the same position as the resected native humeral head. It will allow for variable adjustments for neck angle as well as varus/valgus variances in the neck resection. The humeral heads will be available in multiple diameters and head heights in order to better replicate the normal anatomic range of sizes in patient anatomy.

The total system will consist of an array of sizes of humeral components, humeral heads, and glenoid components manufactured from the exact same materials as the predicate devices.

Intended Use:
The Javelin Shoulder is intended for use in total and hemi-arthroplasty of the shoulder. It is meant to replace the natural humeral head and/or glenoid to relieve pain and reconstruct the joint to re-establish as much normal joint function as possible. The humeral component is for cemented and uncemented use. The glenoid component is for cemented use only.

The indications for use of the Javelin Shoulder when used as a total or hemi-shoulder include:
- Aseptic necrosis of the humeral head.
- Painful, disabling joint disease of the shoulder resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Proximal humeral fracture and/or dislocation.
- Clinical management problems where arthrodesis or alternative reconstruction techniques are
  less likely to achieve satisfactory results.

Additional indications for use as a total shoulder include:
- Revision of previous unsuccessful total shoulder replacement, resurfacing or other procedure.

Substantial Equivalence:
The features of the Javelin Shoulder are substantially equivalent to the corresponding features of the predicate components. Testing was performed to determine the subject components met the performance criteria. In addition, the intended use, material, manufacturing methods, packaging, and sterilization of the predicate and subject components are identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2005

Ms. Karen Ariemma
Regulatory Affairs Specialist
Stryker Orthopaedics
325 Corporate Drive
Mahway, New Jersey 07430

Re: K040432
Trade/Device Name: Javelin Shoulder
Regulation Number: 21 CFR 888.3660, 21 CFR 888.3690
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis, Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: II
Product Code: KWS, HSD
Dated: October 13, 2004
Received: October 14, 2004

Dear Ms. Ariemma:

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,

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

Indications for Use

510(k) Number (if known): K040432

Device Name: Javelin Shoulder

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- Revision of previous unsuccessful total shoulder replacement, resurfacing or other procedure.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 K040432