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510(K) Summary
of Safety and Effectiveness

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the Contoured Articular Prosthetic (CAP) Humeral Head Resurfacing Prosthesis.

Submitted By: STD Manufacturing, Inc.
1063 Turnpike Street
Stoughton, MA 02072
(781) 828-4400

Date: September 16, 2002

Contact Person: Steven W. Ek
VP Engineering

Proprietary Name: Contoured Articular Prosthetic (CAP)
Humeral Head Resurfacing System

Common Name: Hemi-shoulder resurfacing prosthesis

Classification Name: Prosthesis, Shoulder, Hemi-, Humeral, Metallic
Orthopedic
21 CFR § 888.3690
Class II

Product Code: HSD

Intended Use:

The Contoured Articular Prosthetic (CAP) System is intended for the reconstruction of painful and/or severly disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. The device is a single use implant intended to be used with bone cement.

Device Description:

The Contoured Articular Prosthetic (CAP) consists of two components, a taper post component and an articular component, that mate together via a taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/ prosthetic interface.

The taper post component is manufactured of a Ti-6Al-4V ELI alloy per ASTM F136. The taper post has a tapering distal tip, a full-length cannulation, and a proximal female taper bore. The taper post is available in a 25mm and 30mm length to provide for variation in humeral head size.

The articular component is a dome shaped component manufactured of a Cobalt-Chromium-Molybdenum alloy per ASTM F799 and ASTM F1537. The articular component has a bone contact surface that is coated with a CP Titanium coating and a polished articular bearing surface.

Utilizing the drill guide provided within the CAP instrumentation set, a surgeon is able to define a working axis that is normal to the articular cartilage surface at the site of the defect. After drilling a pilot hole, the taper post is driven into place using the trial cap to ensure that the surface of the articular component will be tangent and congruent to the existing cartilage surface when seated. Using the contact probe instrument corresponding to the implant diameter, offset measurements are taken to define the topography of the patients surrounding articular surface by revolving the probe around a centering shaft coaxial to the working axis of the taper post. With these offset measurements, the surgeon is able to select the articular component from a range of sizes that will allow it to seat flush to the surrounding articular surface. Offset increments in .5mm sizes will allow for an optimal fit to the existing articular cartilage.

A reamer, which matches the articular component internal geometry is used to prepare the site for the prosthetic to be implanted. This allows for a precise fit of the implant to the prepared site and minimizes bone resection, so as to provide minimal impact to any future arthroplasty procedure. The articular component is then impacted to seat the taper interlock between the two components.

Substantial Equivalence Information:

The intended use, materials, and application of the candidate device are substantially equivalent to those of the following predicate devices:

Copeland Resurfacing Heads (K003044, K010664)
Buechel-Pappas Humeral Head Resurfacing Component (K992394)

Potential risks associated with the candidate device are the same as with other joint prosthetic devices. These include, but are not limited to:

- Reaction to the bone cement
- Reaction to the implant materials
- Nerve palsy
- Embolus
- Implant loosening/ migration
- Infection
- Delayed wound healing
- Damage to the implants
- Excessive wear
- Hematoma
- Need for Revision
- Incomplete resolution of symptoms

The device is technically easy to implant, and offers the surgeon a high degree of precision and flexibility in sizing and fitting the articular component to the existing anatomy. A minimal amount of bone and articular cartilage resection is also offered by the device.

Additional materials, manufacturing, and performance data to support the safety and effectiveness of the CAP System are provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2003

Mr. Steven W. Ek
Vice President of Engineering
STD Manufacturing, Inc.
1063 Turnpike Street
Stoughton, Massachusetts 02072

Re: K023096
Trade/Device Name: Contoured Articular Prosthetic (CAP) Humeral Head Resurfacing System
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder Joint Humeral (hemi-shoulder) Metallic Uncemented Prosthesis
Regulatory Class: Class II
Product Code: HSD
Dated: January 9, 2003
Received: January 10, 2003

Dear Mr. Ek:

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.

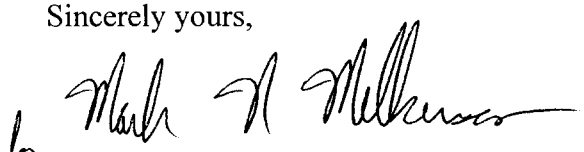
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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 Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: **K023096**

Device Name: **Humeral Head Resurfacing Prosthesis**

Indications for Use:

For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. The device is a single use implant intended to be used with bone cement.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109

Over-The Counter Use _____

(Optional Format 1-2-96)

for Mark N Milhous

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

510(k) Number K023096