K991603

JUN 29 1999

Summary of Safety and Effectiveness

Encore Orthopedics®, Inc.
Debbie De Los Santos
9800 Metric Blvd.
Austin, TX 78758
(512) 834-6237

Common Name: Shoulder prosthesis

Classification Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660 and Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis per 21 CFR 888.369

Description: The humeral stem is manufactured from wrought/forged titanium alloy(Ti-6Al-4V) that conforms to ASTM F136. The entire stem has heavy grit blasting to a surface roughness that ranges from 4μm to 6μm.

The proximal body is rectangular in cross-sectional geometry and tapers proximal to distal. The distal stem is cylindrical with four flutes. Anterior, posterior and lateral fins are located on the proximal body to help provide rotational stability. The fins have suture holes to allow reattachment of soft tissue and bone fragments in the case of proximal humeral fracture. A suture hole is also placed medially through the proximal body just below the collar.

A collar is present on the anterior, posterior and medial faces of the proximal body to resist stem subsidence. A 135° neck stem angle is incorporated. The stem has a female Morse type taper to receive modular humeral heads.

Intended Use: This humeral stem will be used as part of a total shoulder system intended for treatment of patients who are candidates for total shoulder arthroplasty because the natural humeral head and/or glenoid has been affected by osteoarthritis, inflammatory arthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis or proximal humeral fracture, and revision arthroplasty where bone loss is minimal. The humeral stem may be used with or without bone cement. These devices are intended to aid the surgeon in relieving the patient of shoulder pain and restoring shoulder motion.

Comparable Features to Predicate Device(s):
This device has the same design and indications as the humeral stem included in the Total Shoulder System (Encore).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 1999

Ms. Debbie De Los Santos
Encore Orthopedics
Regulatory/Clinical Specialist
9800 Metric Blvd.
Austin, Texas 78758

Re: K991603
Trade Name: Grit Blasted Humeral Stem
Regulatory Class: III
Product Code: KWT
Dated: May 7, 1999
Received: May 10, 1999

Dear Ms. De Los Santos:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Grit Blasted Humeral Stem

Indications For Use:

Grit Blasted Humeral Stem
Indications For Use

This humeral stem will be used as part of a total shoulder system intended for treatment of patients who are candidates for total shoulder arthroplasty because the natural humeral head and/or glenoid has been affected by osteoarthritis, inflammatory arthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis or proximal humeral fracture, and revision arthroplasty where bone loss is minimal. The humeral stem may be used with or without bone cement. These devices are intended to aid the surgeon in relieving the patient of shoulder pain and restoring shoulder motion.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OROver-The-Counter Use ____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)_

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991603