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DEC 1 3 2001

A 510(k) Summary of Safety and Effectiveness

Submitter's name:	Smith & Nephew, Inc., Orthopaedic Division
Submitter's address:	1450 Brooks Road, Memphis, TN 38116
Submitter's telephone number:	901-399-6487
Contact person:	David Henley, Senior Clinical/Regulatory Affairs Specialist
Date summary prepared:	July 25, 2001
Trade or proprietary device name:	3D Humeral Heads
Common or usual name:	Shoulder Joint Prosthesis
Classification name:	21 CFR 888.3660, shoulder joint metal/polymer, semi-constrained cemented prosthesis – Class II

Substantially Equivalent Legally Marketed Devices

- Aequalis™ Shoulder System – Tornier, S.A.
- Anatomica Humeral Stems/Heads – Sulzer Orthopedics

Device Description

3D humeral heads are manufactured from forged cobalt chrome (CoCr) material (ASTM F799) and can be used with existing cobalt chrome humeral stem components from the Cofield^2 Total Shoulder System previously cleared from market. 3D taper sleeves are manufactured from titanium (Ti-6Al-4V) material conforming to the requirements of ASTM F1472.

Device Intended Use

The subject humeral head devices can be mated with approved humeral stem components from the Cofield^2 Total Shoulder System previously cleared for market under K955767. 3D Humeral Heads are indicated for use as orthopedic implants for the partial or total replacement of the human shoulder joint articulating either directly against the glenoid face or a compatible glenoid component, respectively. 3D Humeral Heads are intended for use with bone cement only (cemented fixation) and for single use only. 3D Humeral Heads are intended for the following indications:

Proximal Humeral Prosthesis – (1) complex, acute fractures or fracture-dislocations of the humeral head (e.g. trauma – three and four-part injuries in the Neer classification, or head splitting, or head impression fractures); (2) complex, chronic fractures or fracture-dislocations of the humeral head with malunion, non-union of a small osteoporotic head fragment, or chronic dislocation with loss of humeral head cartilage, or large impression fractures; (3) avascular necrosis with intact glenoid cartilage; and (4) selected patients with arthritis who do not have adequate scapular bone to support a glenoid component or must engage in moderately heavy activities.

Total Shoulder Arthroplasty (when used in conjunction with a compatible glenoid component) – severe destruction of the glenohumeral articular surfaces with intractable chronic pain in rheumatoid arthritis, osteoarthritis, traumatic arthritis, cuff tear arthroplasty, ancient septic arthritis, avascular necrosis with secondary glenoid changes, radiation necrosis, and other failed reconstructive procedures.

The assembled humeral stem component (including a 3D Humeral Head) may be used alone for hemiarthroplasty or combined with a Cofield^2 Total Shoulder System glenoid component for use in total shoulder arthroplasty.

Technological Characteristics:
3D Humeral Heads are similar to the legally marketed predicate devices listed above. All of these devices are indicated for total shoulder arthroplasty or hemiarthroplasty, are similar in design to the 3D Humeral Heads and have the same technological characterisitcs.

Performance Characterisitcs:
Mechanical *humeral head distraction* testing and *ion release analysis* was performed on these devices. Results indicate that the subject devices meet or exceed acceptable performance. Data indicate that 3D Humeral Heads are substantially equivalent to legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2001

Mr. David Henley
Senior Clinical/Regulatory Affairs Specialist
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K012378
Trade/Device Name: 3D Humeral Heads
Regulation Number: 21 CFR §888.3660 and §888.3690
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis; Shoulder joint humeral (hemi-shoulder) metallic cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWS & HSD
Dated: October 25, 2001
Received: October 26, 2001

Dear Mr. Henley:

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.

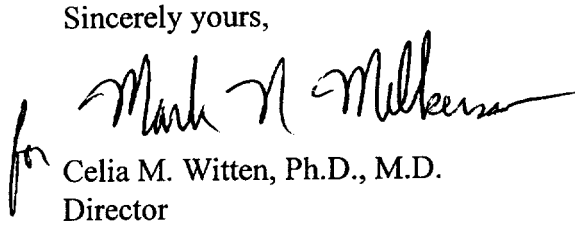
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications Enclosure

510(k) Number (if known): **K012378**

Device Name: **3D Humeral Heads**

Indications for Use:

When used with an appropriate humeral stem from the Cofield^2 Total Shoulder System, **3D Humeral Heads** are indicated for use as orthopedic implants for the partial or total replacement of the human shoulder joint articulating either directly against the glenoid face or a compatible glenoid component from the Cofield^2 or Neer III Total Shoulder Systems, respectively. When used with an appropriate humeral stem, **3D Humeral Heads** are intended for use with bone cement only (i.e. cemented fixation) and for single use only. **3D Humeral Heads** are intended for the following indications:

Proximal Humeral Prosthesis – (1) complex, acute fractures or fracture-dislocations of the humeral head (e.g. trauma – three and four-part injuries in the Neer classification, or head splitting, or head impression fractures); (2) complex, chronic fractures or fracture-dislocations of the humeral head with malunion, non-union of a small osteoporotic head fragment, or chronic dislocation with loss of humeral head cartilage, or large impression fractures; (3) avascular necrosis with intact glenoid cartilage; and (4) selected patients with arthritis who do not have adequate scapular bone to support a glenoid component or must engage in moderately heavy activities.

Total Shoulder Arthroplasty (when used in conjunction with a compatible glenoid component as described above) – severe destruction of the glenohumeral articular surfaces with intractable chronic pain in rheumatoid arthritis, osteoarthritis, traumatic arthritis, cuff tear arthroplasty, ancient septic arthritis, avascular necrosis with secondary glenoid changes, radiation necrosis, and other failed reconstructive procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhoan

(Division Sign-Off)
Division of General, estorative
and Neurological De ces

510(k) Number K012378

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use ____
(Optional Format 1-2-96)