MAR 0 4 2003

K030344

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510(k) Summary
Modular Neer 3 Humeral Stems and Humeral Heads

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:	January 30, 2003
Trade or proprietary device name:	**Modular Neer 3 Humeral Stems and 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
Modular Neer 3 Humeral Stems and Humeral Heads are substantially equivalent to Smith & Nephew Cofield^2 Total Shoulder System humeral stems and humeral heads (K955767 and K003566), Tornier, S.A. Aequalis™ Shoulder System (K952928), and the New Zimmer Shoulder System (K982981).

Device Description
The subject devices are modular humeral stems and humeral heads. They are designed for use with existing Neer II, Neer III, and Cofield^2 Total Shoulder System glenoid components.

Device Intended Use
Modular Neer 3 Humeral Stems and 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. Modular Neer 3 Humeral Stems and Humeral Heads are intended for use with bone cement (cemented fixation) and for single use only. Modular Neer 3 Humeral Stems and 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.

Technological and Performance Characteristics:
Modular Neer 3 Humeral Stems and Humeral Heads are similar to the legally marketed predicate devices listed above. All of these devices are indicated for total shoulder arthroplasty or hemiarthroplasty. They are similar in design to the subject devices and have the same technological characteristics. The safety and effectiveness for the subject devices is adequately supported by test data, material information, and substantial equivalence information provided in this Special 510(k) Premarket Notification. Design Verification Test results indicate that the subject devices meet the requirements of the applicable FDA guidance documents.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 4 2003

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

Re: K030344
Trade/Device Name: Modular Neer 3 Humeral Stems and Heads
Regulation Number: 7821 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS
Dated: January 30, 2003
Received: February 3, 2003

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.

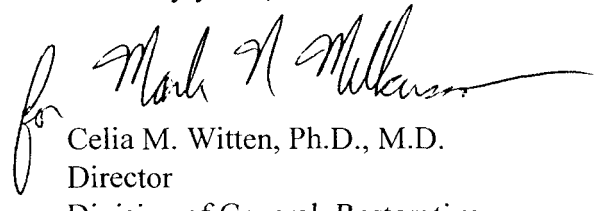
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), 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) you may obtain. 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,



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): K030344

Device Name: **Modular Neer 3 Humeral Stems and Humeral Heads**

Indications for Use:

Modular Neer 3 Humeral Stems and 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. **Modular Neer 3 Humeral Stems and Humeral Heads** are intended for use with bone cement (cemented fixation) and for single use only. **Modular Neer 3 Humeral Stems and Humeral Heads** are intended for the following indications:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

Division Sign-Off
Division of General Restorative
and Neurological Devices

510(k) Number K030344

Prescription Use ✓ (Per 21 CFR 801.109)

OR

Over-the-Counter Use No (Optional Format 1-2-96)