

MAY 23 2000

SUMMARY OF SAFETY AND EFFECTIVENESS

K994350

Submitter's Name	Smith & Nephew, Inc., Orthopaedic Division
Submitter's Address	1450 East Brooks Road, Memphis, Tennessee 38116
Submitter's Telephone No.	901-399-5363
Contact Person	Neal Defibaugh, Manager Clinical/Regulatory Affairs
Date of Summary	April 20, 2000
Proprietary Name	Neer III Total Shoulder System
Device Common Name	Shoulder Joint Prosthesis
Device Classification	Shoulder Joint metal/polymer semi-constrained cemented prosthesis, 21 CFR 888.3660 – Class III

Substantial Equivalent Information

The *Neer III Total Shoulder System* is similar to the following shoulder systems:

1. *Neer II* Total Shoulder System - 3M
2. Modular Total Shoulder System – 3M
3. Aequalis Shoulder System – Tornier S.A.

All of the devices listed above are indicated for the same use as total shoulder systems, and are similar in design to the *Neer III Total Shoulder System*. The safety and effectiveness of the *Neer III Total Shoulder System* is based on the long history of use of these devices in the market place.

Device Description

Neer III humeral stems are manufactured from cast CoCr (cobalt chrome) alloy and are available in three stem diameters (8, 10 & 12mm). Four head heights, 15, 19, 22 & 26mm, are available, to allow accurate tensioning of the joint intra-operatively. The 25mm radius of curvature of the heads is constant throughout the range to permit the stem to be used as a total shoulder replacement in conjunction with various glenoid components. Suture-wire holes are located in two laterally orientated fins to optimize re-attachment of the tuberosities.

The implants in the system are intended for cemented fixation into a prepared humeral canal. *Neer III* humeral stems can be used in conjunction with a compatible glenoid component, such as Neer II Shoulder glenoid components, Cofield Modular Shoulder glenoid components, Anatomic glenoid components, or in a hemi-arthroplasty against an unresurfaced glenoid process.

Indications for Use

The *Neer III Total Shoulder System* is indicated for use as an orthopedic implant for the partial or total replacement of the human shoulder joint articulating either directly against the glenoid face or a compatible glenoid component, respectively.

The *Neer III Total Shoulder System* is intended for the following:

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, nonunion 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.

This device is intended only for cemented fixation.

Technological Characteristics:

The *Neer III Total Shoulder System* is substantially equivalent to the above predicate devices. The *Neer III* device is a modification of the Neer II device and has the same technological characteristics as the Neer II device and the other predicate devices. Range of Motion, finite element analysis, fatigue testing, stem strength, and package integrity testing were performed on the *Neer III* prosthesis. Test results were consistent with the Neer II and predicate devices. The Anatomic Glenoid is substantially equivalent to the Neer II UHMWPE glenoid component predicate device. It is manufactured of the same material with the only difference being a more anatomical “pear-shaped” design.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Neal Defibaugh
Manager Clinical/Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K994350
Trade Name: Neer III Total Shoulder System
Regulatory Class: III
Product Code: KWS and HSD
Dated: April 27, 2000
Received: April 28, 2000

Dear Mr. Defibaugh:

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 control provisions of the Act. The general control 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.

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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 at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Donna R. Lochner

 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): K994350

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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)

Dianne R. Lockner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994350

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The Counter Use
(Optional Format 1-2-96)