510k summary

K121714 (1 of 3)

Summary of Safety and Effectiveness
Shoulder System Instruments
Smith & Nephew, Inc.

SEP 7 2012

Contact Person and Address
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Smith & Nephew, Inc.
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Date of Summary: September 7, 2012

Name of Device: Shoulder System Instruments
Common Name: Orthopaedic Surgical Instrumentation
Device Classification Name and Reference:
21 CFR 888.3660 – Shoulder joint metal/polymer semi-constrained cemented prosthesis
21 CFR 888.3690 – Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Device Class: Class II
Panel Code: Orthopaedics/87
Predicate Devices:
Cofield Shoulder System cemented (KI955767);
Cofield Shoulder System (K855183);
Cofield Modular Shoulder System (K955767);
Cofield Eccentric and Lateral offset Humeral Heads (K003566);
PROMOS Shoulder (K032126);
PLUS PROMOS Modular Shoulder System (K063578);
Cofield^2 Total Shoulder System (K070565);
PROMOS Reverse Shoulder System (K081016)

Device Description

Subject of this Traditional 510(k) Premarket Notification are the Smith & Nephew, Inc. Shoulder System Instruments. The subject devices are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Shoulder Systems and their cleared Indications for Use. Smith & Nephew Shoulder System Instruments can be organized into instrument families which are categorized as follows: Trials, Guides, Insertion/Extraction, Holding, Impactors, and Cutting Instruments.

Intended Use / Indications for Use

Smith & Nephew Shoulder Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Shoulder Systems and their cleared Indications for Use.

Cofield Shoulder Systems
Proximal Humeral Prosthesis

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1. Complex, acute fractures or fracture-dislocations of the humeral head (e.g., the 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.
4. Selected patients with arthritis who do not have adequate scapular bone to support a glenoid component or who must engage in moderately heavy activities.

Total Shoulder Arthroplasty

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 Cofield Shoulder System contains devices which are intended only for use only with bone cement and are single use devices.

Cofield^2 Shoulder System

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.
4. Selected patients with arthritis who do not have adequate scapular bone to support a glenoid component or who must engage in moderately heavy activities.

Total Shoulder Arthroplasty

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 Cofield^2 Shoulder System includes humeral devices which are intended for use with or without bone cement and are single use devices. Cofield^2 Shoulder System glenoid components are intended for use only with bone cement and are single use devices.

PROMOS Shoulder Systems

Indications for the PROMOS Modular Shoulder System (Standard)

- Advanced wear of the shoulder joint due to degenerative, post-traumatic or inflammatory arthritis
- Avascular necrosis of the humeral head
- Complex fractures of the proximal humerus
- Functional impairment especially in the case of post-traumatic loss of the joint configuration

The humeral stem and body components are intended for cementless use.
The glenoid component is for use with bone cement only.

Indications for the PROMOS Modular Shoulder System (Reverse)

- The PROMOS Reverse Shoulder is indicated for use in a grossly deficient rotator cuff joint with severe arthropathy or a previous failed joint replacement with a grossly deficient rotator cuff joint
- The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The humeral stem and body components are intended for cementless use.
The glenoid baseplate is intended for cementless application with the addition of screws for fixation.

Substantial Equivalence Information

The device specific instruments associated with the implant devices with which they are used are considered substantially equivalent to previously cleared device specific instruments in that both subject and predicate instruments:

- Share the same raw materials;
- Are manufactured though the same processes;
- Utilize the same sterilization procedures; and
- Have similar nature of body contact

The Smith and Nephew Shoulder System Instruments are similar in design and function to competing shoulder surgical instrumentation on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew, Incorporated
% Mr. Bradley Heil
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

SEP 7 2012

Re: K121714
Trade/Device Name: Smith & Nephew Incorporated Shoulder System Instruments
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD
Dated: June 8, 2012
Received: June 11, 2012

Dear Mr. Heil:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Cofield² Shoulder Systems
Indications for Use:

Smith & Nephew Cofield² Shoulder Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Cofield² Shoulder Systems and their cleared Indications for Use.

Indications for Shoulder Replacement

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.
4. Selected patients with arthritis who do not have adequate scapular bone to support a glenoid component or who must engage in moderately heavy activities.

Total Shoulder Arthroplasty

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 Cofield² Shoulder System includes humeral devices which are intended for use with or without bone cement and are single use devices. Cofield² Shoulder System glenoid components are intended for use only with bone cement and are single use devices.

Prescription Use	X	AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K121714

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Indications for Use

510(k) Number (if known):

Device Name: Cofield Shoulder Systems
Indications for Use:

Smith & Nephew Cofield Shoulder Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Cofield Shoulder Systems and their cleared Indications for Use.

Indications for Shoulder Replacement

Proximal Humeral Prosthesis

1. Complex, acute fractures or fracture-dislocations of the humeral head (e.g., the 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.
4. Selected patients with arthritis who do not have adequate scapular bone to support a glenoid component or who must engage in moderately heavy activities.

Total Shoulder Arthroplasty

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 Cofield Shoulder System contains devices which are intended only for use with bone cement and are single use devices.

Prescription Use	X	AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K121714

K121714(3/3)

Indications for Use

510(k) Number (if known):

Device Name: PROMOS Shoulder Systems
Indications for Use:
Smith & Nephew Shoulder Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Shoulder Systems and their cleared Indications for Use.

The PROMOS Modular Shoulder System (Standard) is indicated for:

- Advanced wear of the shoulder joint due to degenerative, post-traumatic or inflammatory arthritis
- Avascular necrosis of the humeral head
- Complex fractures of the proximal humerus
- Functional impairment espedally in the case of post-traumatic loss of the joint configuration

The humeral stem and body components are intended for cementless use.
The glenoid component is for use with bone cement only.

The PROMOS Modular Shoulder System (Reverse) is indicated for the following:

- The PROMOS Reverse Shoulder is indicated for use in a grossly deficient rotator cuff joint with severe arthropathy or a previous failed joint replacement with a grossly deficient rotator cuff joint
- The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The humeral stem and body components are intended for cementless use.
The glenoid baseplate is intended for cementless application with the addition of screws for fixation.

Prescription Use	X	AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)	

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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