U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K061243 - 95 pages
COMPANY:	SMITH & NEPHEW, INC. (SMITNEPH)
PRODUCT:	PROSTHESIS, HIP, HEMI-, FEMORAL, METAL (KWL)
SUMMARY:	Product: SMITH & NEPHEW MODULAR FEMORAL HEAD
DATE REQUESTED:	Jan 4, 2016
DATE PRINTED:	Jan 4, 2016
Note:	Printed

K061243 page 1 of 1

510(K) Summary

JUL 17 2006

Smith & Nephew Modular Femoral Heads

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 East Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6707
CONTACT PERSON:	Gino J. Rouss
DATE SUMMARY PREPARED:	May 2, 2006
TRADE OR PROPRIETARY DEVICE NAME:	Smith & Nephew Modular Femoral Heads
COMMON OR USUAL NAME:	Artificial Hip Replacement Prosthesis
CLASSIFICATION NAME:	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis, 21 CFR 888.3360
DEVICE CLASS:	Class II
PANEL CODE:	KWL – prosthesis, hip, hemi-, femoral, metal Orthopedics Panel/87

A. INTENDED USE:

The Smith & Nephew Modular Femoral Heads are indicated for the following:

- Noninflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis;
- rheumatoid arthritis;
- arthritis secondary to a variety of diseases and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis;
- revision procedures where other treatments have failed; and
- treatment of proximal femoral non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement.

The modular femoral heads are for single use only and are intended to be used as part of a hemi-hip replacement system when articulating against the natural acetabulum.

B. DEVICE DESCRIPTION:

New cobalt chrome (CoCr) modular femoral heads have been designed and developed by Smith & Nephew Orthopaedics. The subject devices are offered in sizes ranging from 38-58mm and feature a 12/14 taper interface to allow the components to be used in conjunction with existing Smith & Nephew femoral components. The overall designs of the components are based upon existing Uni-polar implants subject of K896580.

C. SUBSTANTIAL EQUIVALENCE INFORMATION:

The Smith & Nephew Modular Femoral Heads are similar to the following commercially available devices regarding design features, overall indications, and materials:

- Smith & Nephew Uni-Polar Head (K896580)
- Smith & Nephew Global Bipolar System (K023743)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2006

Smith & Nephew, Inc.
% Mr. Gino J. Rouss, MS
Orthopaedics Division
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

Re: K061243
Trade/Device Name: Smith & Nephew Modular Femoral Head
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWL
Dated: May 1, 2006
Received: May 3, 2006

Dear Mr. Rouss:

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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 240-276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchwald
for

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

Enclosure

Indications for Use

510(k) Number (if known): K061243

Device Name: Smith & Nephew Modular Femoral Heads

Indications for Use:

The Smith & Nephew Modular Femoral Heads are indicated for the following:

- Noninflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis;
- rheumatoid arthritis;
- arthritis secondary to a variety of diseases and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis;
- revision procedures where other treatments have failed; and
- treatment of proximal femoral non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement.

The modular femoral heads are for single use only and are intended to be used as part of a hemi-hip replacement system when articulating against the natural acetabulum.

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)

Barbara Buchman
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061243

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2006

Smith & Nephew, Inc.
% Mr. Gino J. Rouss, MS
Orthopaedics Division
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

Re: K061243
Trade/Device Name: Smith & Nephew Modular Femoral Head
Regulation Number: 21 CFR 888.3360
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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.

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Sincerely yours,

Barbara Bucher MD
for

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

Enclosure

Indications for Use

510(k) Number (if known): K061243

Device Name: Smith & Nephew Modular Femoral Heads

Indications for Use:

The Smith & Nephew Modular Femoral Heads are indicated for the following:

- Noninflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis;
- rheumatoid arthritis;
- arthritis secondary to a variety of diseases and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis;
- revision procedures where other treatments have failed; and
- treatment of proximal femoral non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement.

The modular femoral heads are for single use only and are intended to be used as part of a hemi-hip replacement system when articulating against the natural acetabulum.

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

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061243

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 05, 2006

SMITH & NEPHEW, INC.
ORTHOPAEDIC DIVISION
1450 BROOKS RD.
MEMPHIS, TN 38116
ATTN: GINO ROUSS

510(k) Number: K061243
Received: 03-MAY-2006
Product: SMITH & NEPHEW
MODULAR FEMORAL HEAD

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

K061243

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4) [redacted]
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

-->

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

SMITH AND NEPHEW INC
1450 BROOKS ROAD
MEMPHIS TN 38116
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
510123924

2. CONTACT NAME
Gino Rouss

2.1 E-MAIL ADDRESS
gino.rouss@smithnephew.com

2.2 TELEPHONE NUMBER (include Area code)
901-399-6707

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
NO DATA

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
(b) (4) [redacted] 26-Apr-2006

Form FDA 8601 (08/2003)

Close Window

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Orthopaedics
Smith & Nephew, Inc.
1450 Brooks Rd.
Memphis, TN 38116 U.S.A.

901-396-2121
800-821-5700
www.smith-nephew.com

We are **smith&nephew**

K 22

May 1, 2006

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

RE: Smith & Nephew Modular Femoral Head: Abbreviated 510(k) Notification

Dear Sir or Madam:

We would like for this letter to serve as premarket notification of our intent to market the Smith & Nephew Modular Femoral Heads. The design and materials used for these components are substantially equivalent to devices contained within the Smith & Nephew Uni-Polar Femoral Head System cleared under 510(k) Notification K896580.

Smith & Nephew is submitting this abbreviated 510(k) in accordance with the guidance titled *"Guidance Document for Testing Acetabular Cup Prosthesis,"* dated May 1995. The document has been organized in outline format for ease of locating specific content.

We consider our intent to market these devices to be confidential commercial information, and therefore exempt from public disclosure. We believe this information fulfills the requirements for the present Abbreviated 510(k) submission. If additional clarification or information is required, please contact me directly at (901) 399-6707 or via email at gino.rouss@smithnephew.com.

Sincerely,

Gino Rouss

Gino J. Rouss, MS
Regulatory Affairs Specialist
Smith & Nephew Orthopaedics

FDA/CDRH/CDRH
MAY -3 P 1:45

OR 11 35

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
05/02/2006	(b) (4) [redacted]	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☑ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☑ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
Amendment	Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
Supplement	Supplement			
	Report			
	Report Amendment			

Have you used or cited Standards in your submission? ☑ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Smith & Nephew, Inc.	Establishment Registration Number *(if known)*: 1020279		
Division Name *(if applicable)*: Orthopaedics	Phone Number *(including area code)*: (901) 399-6707		
Street Address: 1450 Brooks Road	FAX Number *(including area code)*: (901) 398-5146		
City: Memphis	State / Province: TN	ZIP/Postal Code: 38116	Country: USA
Contact Name: Gino Rouss			
Contact Title: Regulatory Affairs Specialist	Contact E-mail Address: gino.rouss@smithnephew.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name:			
Division Name *(if applicable)*:	Phone Number *(including area code)*: ( )		
Street Address:	FAX Number *(including area code)*: ( )		
City:	State / Province:	ZIP/Postal Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

PSC Media Arts (301) 443-1090 EF

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SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

☐ Process change:
- Manufacturing
- Sterilization
- Packaging
- Other *(specify below)*

☐ Response to FDA correspondence:

☐ Change in design, component, or specification:
- Software / Hardware
- Color Additive
- Material
- Specifications
- Other *(specify below)*

☐ Labeling change:
- Indications
- Instructions
- Performance
- Shelf Life
- Trade Name
- Other *(specify below)*

☐ Location change:
- Manufacturer
- Sterilizer
- Packager

☐ Report Submission:
- Annual or Periodic
- Post-approval Study
- Adverse Reaction
- Device Defect
- Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

☐ Change in:
- Correspondent / Applicant
- Design / Device
- Informed Consent
- Manufacturer
- Manufacturing Process
- Protocol - Feasibility
- Protocol - Other
- Sponsor

☐ Report submission:
- Current Investigator
- Annual Progress Report
- Site Waiver Report
- Final

☐ Repose to FDA Letter Concerning:
- Conditional Approval
- Deemed Approved
- Deficient Final Report
- Deficient Progress Report
- Deficient Investigator Report
- Disapproval
- Request Extension of Time to Respond to FDA
- Request Meeting
- Request Hearing

☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☑ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

☐ Other Reason *(specify)*:

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	KWL	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K896580	1	Uni-Polar Femoral Head	1	Smith & Nephew, Inc.
2	K934353	2	Zirconium Alloy Uni-Polar Femoral Head	2	Smith & Nephew, Inc.
3	K023743	3	Global Bipolar System	3	Smith & Nephew, Inc.
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

	Trade or Proprietary or Model Name for This Device		Model Number
1	Smith & Nephew Modular Femoral Head	1	n/a
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
KWL	21 CFR 888.3360	[ ] Class I [x] Class II [ ] Class III [ ] Unclassified

Classification Panel

Orthopedics Panel/87

Indications *(from labeling)*

-Noninflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis;
-rheumatoid arthritis;
-arthritis secondary to a variety of diseases and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis;
-revision procedures where other treatments have failed; and
-treatment of proximal femoral non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☑ Original ☐ Add ☐ Delete	FDA Establishment Registration Number: 1020279	☑ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name: Smith & Nephew, Inc.		Establishment Registration Number: 1020279	
Division Name *(if applicable)*: Orthopaedics		Phone Number *(including area code)*: (901) 399-6707	
Street Address: 1450 Brooks Road		FAX Number *(including area code)*: (901) 398-5146	
City: Memphis		State / Province: TN	ZIP/Postal Code: 38116 / Country: USA
Contact Name: Gino Rouss	Contact Title: Regulatory Affairs Specialist	Contact E-mail Address: gino.rouss@smithnephew.com	

☑ Original ☐ Add ☐ Delete	FDA Establishment Registration Number: 3005623319	☑ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name: Smith & Nephew Orthopaedics Limited		Establishment Registration Number: 3005623319	
Division Name *(if applicable)*: Orthopaedics		Phone Number *(including area code)*: (901) 399-6670	
Street Address: Hanbury Road, Stoke Prior		FAX Number *(including area code)*: (901) 398-5146	
City: Bromsgrove		State / Province:	ZIP/Postal Code: B60 4AD / Country: UK
Contact Name: John Reabe	Contact Title: Director, Regulatory Affairs	Contact E-mail Address: john.reabe@smithnephew.com	

(b)(4) Contract Manufacturer

[redacted]

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	F75	ASTM	Standard Specification for Cobalt-28 Chromium-6 Molybd		12/10/2001
2	14630	ISO	Non-active Surgical Implants - General Requirements		02/19/1998
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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Smith & Nephew Modular Femoral Head

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Smith & Nephew Modular Femoral Heads

Executive Summary

Device Description

Subject of this premarket notification are new cobalt chrome (CoCr) modular femoral heads that are offered in sizes ranging from 38-58mm. The components feature a 12/14 taper interface, with each size being offered with a -8, -4, +0, or +4mm offset. The modular femoral heads are intended to be used as part of a hemi-hip replacement system when articulating against the natural acetabulum and are compatible with existing Smith & Nephew femoral components.

Indications for Use

The Smith & Nephew Modular Femoral Heads are indicated for the following:

- Noninflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis;
- rheumatoid arthritis;
- arthritis secondary to a variety of diseases and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis;
- revision procedures where other treatments have failed; and
- treatment of proximal femoral non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement.

The modular femoral heads are for single use only and are intended to be used as part of a hemi-hip replacement system when articulating against the natural acetabulum.

Device Comparison

The overall designs and the indications for use for the Smith & Nephew Modular Femoral Heads are substantially equivalent to the Smith & Nephew Uni-Polar Head, the Smith & Nephew Zirconium Alloy Uni-Polar Head, and the Smith & Nephew Global Bipolar System cleared for market under 510(k) Notifications K896580, K934353, and K023743, respectively.

The material used in the manufacturing of the Smith & Nephew Modular Femoral Heads is the same material used to manufacture hip system components which have been cleared in premarket notifications listed below.

Predicate Hip Systems Containing the Same Material

Manufacturer	Description	510(K)	Clearance Date
Smith & Nephew, Inc.	Global Bipolar System	K023743	01/23/03
Smith & Nephew, Inc.	Uni-Polar Head	K896580	02/15/90

In summary, the Smith & Nephew Modular Femoral Heads are similar in design, function, intended use, and material composition to currently marketed predicate devices. Although the Modular Femoral Heads are not identical to all aspects of the predicate devices, any differences that exist have been shown to not significantly affect the safety and effectiveness of the device. As such, the Smith & Nephew Modular Femoral Heads are considered substantially equivalent to commercially available hip prostheses.

Testing

This Abbreviated 510(k) has been prepared to address the requirements of the following Guidance Document:

- *Guidance for Testing Acetabular Cup Prostheses,* dated May 1995

A summary report describing how the applicable guidance document was used during device development and testing to address risks associated with the subject devices is included as **Exhibit 6**.

I. ADMINISTRATIVE INFORMATION

A. Truthful and Accurate Statement

The required Truthful and Accurate Statement is provided as **Exhibit 1**.

B. 510(k) Summary and Indications Enclosure

The required 510(k) Summary and Indications Enclosure is provided as **Exhibit 2**.

C. Class III Summary and Certification

The Smith & Nephew Modular Femoral Heads are Class II devices; therefore, this section does not apply.

D. Financial Certification and Disclosure Statement

This Abbreviated 510(k) submission for the Smith & Nephew Modular Femoral Heads does not contain clinical data; therefore, this section does not apply.

E. Declaration of Conformity

A Declaration of Conformity to FDA recognized standards is provided as **Exhibit 3**.

F. Manufacturer Identification

Manufacturer's Name:	Smith & Nephew, Inc. Orthopaedic Division 1450 E. Brooks Road Memphis, TN 38116
Establishment Registration Number:	1020279
Primary Contact Person:	Gino J. Rouss Regulatory Affairs Specialist Smith & Nephew Orthopaedics Tel: (901) 399-6707 Fax: (901) 398-5146
Secondary Contact Person:	Jason Sells Regulatory Affairs Specialist Smith & Nephew Orthopaedics Tel: (901) 399-5520 Fax: (901) 398-5146

G. Device Identification

Proprietary Name:	Modular Femoral Head Components
Common Name:	Artificial Hip Replacement Prosthesis
Classification Name and Reference:	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis, 21 CFR 888.3360
Device Classification of Subject Device:	Class II
Classification Name and Reference of Predicate Device:	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis, 21 CFR 888.3360
Device Classification of Predicate Device:	Class II
Device Product Code and Panel Code:	KWL – prosthesis, hip, hemi-, femoral, metal Orthopedics Panel/87

Is the manufacturing site located at a different location from the firm headquarters? Yes

Location: Smith & Nephew Orthopaedics Limited
Saxon Business Park
Hanbury Road, Stoke Prior
Bromsgrove, Worcestershire
United Kingdom

II. DEVICE INFORMATION

A. Intended Use

The Smith & Nephew Modular Femoral Heads feature a 12/14 taper that mates with commercially-available Smith & Nephew femoral stem components. The modular heads are intended to be used as part of a hemi-hip replacement system when articulating against the natural acetabulum.

Indications include the following:

- Noninflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis;
- rheumatoid arthritis;
- arthritis secondary to a variety of diseases and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis;

- revision procedures where other treatments have failed; and
- treatment of proximal femoral non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement.

These indications for use are substantially equivalent to currently marketed Smith & Nephew uni-polar and bipolar hip systems listed below.

Table I: Predicate Device with identical Indications for Use

Description	Submission Number	Clearance Date
Global Bipolar System	K023743	01/23/03
Zirconium Alloy Uni-Polar Head	K934353	04/25/94
Uni-Polar Head	K896580	02/15/90

B. Device Description

Subject of this premarket notification are new cobalt chrome (CoCr) modular femoral heads that are offered in sizes ranging from 38-58mm. The components feature a 12/14 taper interface, with each size being offered with a -8, -4, +0, or +4mm offset. The modular femoral heads are intended to be used as part of a hemi-hip replacement system when articulating against the natural acetabulum and are compatible with existing Smith & Nephew femoral components that have been cleared for market through premarket notifications listed below.

Table II: Previously Cleared Smith & Nephew Femoral Components with 12/14 Taper

Description	Submission Number	Clearance Date
Echelon (Revision) Hip Stems – Porous and Non-porous	K963486	11/27/96
Echelon Primary Hip Stems	K983834	2/24/99
Echelon Hip Stems – HA Coated	K023302	10/25/02
Synergy (Tapered) Hip Stems – Porous and Non-porous	K963509	1/27/97
Synergy (Tapered) Hip Stems – HA Press-fit	K970337	2/28/97
Synergy Cemented Hip Stems	K990369	3/12/99
Synergy Porous Size 8 Hip Stem	K991485	7/12/99
Synergy HA Coated Porous Hip Stems	K002996	12/11/00
Spectron Hip Stems	K970351	2/28/97
Smith & Nephew Modular Hip (Emperion)	K042127	11/19/04
Smith & Nephew Modular Hip (Emperion) – Line Additions	K052426	12/07/05
Platform Hip Stem	K052275	12/07/05
Anthology Hip Stems	K052792	10/07/05

A Representative Engineering print of the Smith & Nephew modular femoral heads is provided in **Exhibit 4**. A component description list is provided in **Exhibit 5**.

C. Materials

The Smith & Nephew modular femoral heads will be manufactured from Cobalt-Chromium-Molybdenum Alloy (Co-Cr-Mo) material conforming to:

ASTM F 75	Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implant Applications

The same material is used to manufacture hip components which have been cleared in premarket notifications listed below:

hip

Table III: Predicate Knee Systems Containing the Same Material

Description	Submission Number	Clearance Date
Global Bipolar System	K023743	01/23/03
Uni-Polar Head	K896580	02/15/90

D. Testing Information

This Abbreviated 510(k) has been prepared to address the requirements of the following Guidance Document:

- *Guidance for Testing Acetabular Cup Prostheses*, dated May 1995

A summary report describing how the applicable guidance document was used during device development and testing to address risks associated with the subject device is included as **Exhibit 6**. Orthopaedic Research Reports and Technical Memorandums provided in **Exhibits 7, 8, 9, and 10** provide detailed information concerning testing regarding the Smith & Nephew modular femoral heads.

A review of the testing has demonstrated that there are no new issues related to the safety or effectiveness of the subject device.

E. Sterilization Information

The Smith & Nephew Modular Femoral Heads are sold sterile, and are intended for single-use only. The components will be sterilized by gamma irradiation.

Additional sterilization information is provided in **Exhibit 11.**

F. Labeling

Carton labels for the Smith & Nephew Modular Femoral Heads are provided in **Exhibit 12**. Product will be labeled with a 5 year expiration date.

Smith & Nephew has conducted both package integrity and sterility testing to support a 5 year expiration date label. Sterility testing data was based on real time testing of recovered product that had been returned after being in the field five or more years. Smith & Nephew has the test data in a report file in Regulatory Affairs to satisfy FDA inspections.

A package insert for the Smith & Nephew Modular Femoral Head components is provided in **Exhibit 13**.

G. Software

This section does not apply.

H. Electromagnetic Compatibility and Electrical Safety

This section does not apply.

I. Substantial Equivalence Information

The overall designs and the indications for use for the Smith & Nephew Modular Femoral Heads are substantially equivalent to the Smith & Nephew Uni-Polar Head, the Smith & Nephew Zirconium Alloy Uni-Polar Head, and the Smith & Nephew Global Bipolar System cleared for market under 510(k) Notifications K896580, K934353, and K023743, respectively.

The material used in the manufacturing of the Smith & Nephew Modular Femoral Heads is the same material used to manufacture hip system components which have been cleared in premarket notifications listed below.

Table IV: Predicate Hip Systems Containing the Same Material

Manufacturer	Description	510(K)	Clearance Date
Smith & Nephew, Inc.	Global Bipolar System	K023743	01/23/03
Smith & Nephew, Inc.	Uni-Polar Head	K896580	02/15/90

In summary, the Smith & Nephew Modular Femoral Heads are similar in design, function, intended use, and material composition to currently marketed predicate devices. Although the Modular Femoral Heads are not identical to all aspects of the predicate devices, any differences that exist have been shown to not significantly affect the safety and effectiveness of the device. As such, the Smith & Nephew Modular Femoral Heads are considered substantially equivalent to commercially available hip prostheses.

Premarket notification information for predicate devices is located in **Exhibit 14**.

Smith & Nephew Modular Femoral Head

List of Exhibits

Exhibit 1	Truthful and Accuracy Statement
Exhibit 2	510(k) Summary of Safety and Effectiveness and Indications Statement
Exhibit 3	Declaration of Conformity
Exhibit 4	Representative Engineering Drawings
Exhibit 5	Component Descriptions
Exhibit 6	Summary Document per *"Guidance Document for Testing Acetabular Cup Prosthesis,"* dated May 1995
Exhibit 7	Memorandum, "ROM for Smith & Nephew Modular Femoral Head", April 2006
Exhibit 8	Orthopaedic Research Report OR-05-07, (b) (4) [redacted]
Exhibit 9	Orthopaedic Research Report OR-06-56, (b) (4) [redacted]
Exhibit 10	Technical Memorandum TM070505, "(b) (4) [redacted]
Exhibit 11	Sterilization Information
Exhibit 12	Sample Carton Labels
Exhibit 13	Sample Package Insert
Exhibit 14	Premarket Notification Information for Predicate Devices

TRUTHFUL AND ACCURATE STATEMENT

I certify that, in my capacity as a Regulatory Affairs Specialist for Smith & Nephew, Inc., Orthopaedic Division, I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Gino J. Rouss

Date: 05/01/06

510(K) Summary

Smith & Nephew Modular Femoral Heads

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 East Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6707
CONTACT PERSON:	Gino J. Rouss
DATE SUMMARY PREPARED:	May 2, 2006
TRADE OR PROPRIETARY DEVICE NAME:	Smith & Nephew Modular Femoral Heads
COMMON OR USUAL NAME:	Artificial Hip Replacement Prosthesis
CLASSIFICATION NAME:	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis, 21 CFR 888.3360
DEVICE CLASS:	Class II
PANEL CODE:	KWL – prosthesis, hip, hemi-, femoral, metal Orthopedics Panel/87

A. INTENDED USE:

The Smith & Nephew Modular Femoral Heads are indicated for the following:

- Noninflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis;
- rheumatoid arthritis;
- arthritis secondary to a variety of diseases and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis;
- revision procedures where other treatments have failed; and
- treatment of proximal femoral non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement.

The modular femoral heads are for single use only and are intended to be used as part of a hemi-hip replacement system when articulating against the natural acetabulum.

B. DEVICE DESCRIPTION:

New cobalt chrome (CoCr) modular femoral heads have been designed and developed by Smith & Nephew Orthopaedics. The subject devices are offered in sizes ranging from 38-58mm and feature a 12/14 taper interface to allow the components to be used in conjunction with existing Smith & Nephew femoral components. The overall designs of the components are based upon existing Uni-polar implants subject of K896580.

C. SUBSTANTIAL EQUIVALENCE INFORMATION:

The Smith & Nephew Modular Femoral Heads are similar to the following commercially available devices regarding design features, overall indications, and materials:

- Smith & Nephew Uni-Polar Head (K896580)
- Smith & Nephew Global Bipolar System (K023743)

Indications for Use

510(k) Number (if known):

Device Name: **Smith & Nephew Modular Femoral Heads**

Indications for Use:

The Smith & Nephew Modular Femoral Heads are indicated for the following:

- Noninflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis;
- rheumatoid arthritis;
- arthritis secondary to a variety of diseases and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis;
- revision procedures where other treatments have failed; and
- treatment of proximal femoral non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement.

The modular femoral heads are for single use only and are intended to be used as part of a hemi-hip replacement system when articulating against the natural acetabulum.

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

Smith & Nephew Modular Femoral Heads

Declaration of Conformity

To the best of my knowledge, the FDA recognized standards that were followed in the design, development, and testing of the Smith & Nephew Modular Femoral Heads are provided in the table below.

FDA Recognized Standards	
Reference Number	**Title of Standard**
ASTM F75	Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implant Applications
ISO 14630: 1997	Non-active Surgical Implants – General Requirements

In addition, the subject device was designed and tested in conformance with the FDA guidance document titled, *"Guidance for Testing Acetabular Cup Prostheses,"* dated May 1995.

Gino Rouss, MS
Regulatory Affairs Specialist
Smith & Nephew, Inc.

05/01/06
Date

b(4)Trade Secret Process- Engineering Design

Smith & Nephew Modular Femoral Heads

Product Descriptions

Modular Femoral Heads
Modular Head 38mm -8mm
Modular Head 42mm -8mm
Modular Head 46mm -8mm
Modular Head 50mm -8mm
Modular Head 54mm -8mm
Modular Head 58mm -8mm
Modular Head 38mm -4mm (Short)
Modular Head 42mm -4mm (Short)
Modular Head 46mm -4mm (Short)
Modular Head 50mm -4mm (Short)
Modular Head 54mm -4mm (Short)
Modular Head 58mm -4mm (Short)
Modular Head 38mm +0mm (Medium)
Modular Head 42mm +0mm (Medium)
Modular Head 46mm +0mm (Medium)
Modular Head 50mm +0mm (Medium)
Modular Head 54mm +0mm (Medium)
Modular Head 58mm +0mm (Medium)
Modular Head 38mm +4mm (Long)
Modular Head 42mm +4mm (Long)
Modular Head 46mm +4mm (Long)
Modular Head 50mm +4mm (Long)
Modular Head 54mm +4mm (Long)
Modular Head 58mm +4mm (Long)

(b)(4) Testing

b(4)Trade Secret Process- Testing

b(4)Trade Secret Process- Testing

Orthopaedics
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

T 901-399-5721
F 901-399-6990
www.smith-nephew.com

We are **smith&nephew**

b(4)Trade Secret Process- Technical Report

[redacted]

Memo

(6)

b(4)Trade Secret Process- Technical Report

b(4)Trade Secret Process- Technical Report

b(4)Trade Secret Process- Technical Report

b(4)Trade Secret Process- Technical Report

b(4)Trade Secret Process- Technical Report

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b(4)Trade Secret Process- Technical Report

Radiation Sterilization Process

Source/Type of Sterilization:	Cobalt 60/Gamma radiation
Sterility Assurance Level:	(b) (4) [redacted]
Type of Cycle:	Overkill
Dosage:	25 Kilo grays minimum
Validation:	Validation is accomplished by following the procedures set forth by the Association for the Advancement of Medical Instrumentation (AAMI) Guideline on Sterilization of healthcare products – Radiation sterilization – Substantiation of 25 kGy as a sterilization dose – Method VD_{max}, AAMI TIR27:2001.
Description of Packaging:	Packaged in a double-pouch. The inner pouch is a polyester laminate, while the outer pouch is Tyvek/Mylar. The double-pouch assembly is placed in a carton with foam packaging to protect the pouches/devices during transport/storage. The entire carton is shrink wrapped.
Pyrogen Statement:	These products are not labeled as "non-pyrogenic." Applications of orthopaedic implants are such that routine pyrogen testing is not required.
Contract Sterilizer:	Swann-Morton (Services) Ltd Owlerton Green, Sheffield South Yorkshire S6 2BJ UK

Smith & Nephew Modular Femoral Heads

Sample Outer Carton Label

REF DL7321 QTY: (1) smith&nephew

MODULAR
FEMORAL HEAD

TETE FEMORALE / HUFTKOPF
CABEZA FEMORAL / TESTA FEMORALE

38MM, -8MM

LOT NO. SAMPLE

LOT SAMPLE

CE 0120

STERILE R

2011/04

CO-CR

MADE IN UNITED KINGDOM

+H435DL73211W

+$SAMPLEWH

Smith & Nephew Orthopaedics Ltd
Bromsgrove England UK B60 3AB

smith&nephew

Endoprostheses Systems

IMPORTANT MEDICAL INFORMATION

EN

SPECIAL NOTE

The indications for using any endoprosthesis, unipolar or bipolar device should be based upon careful patient selection and expectations. The specific components selected should be dependent upon the patient's age, general condition, available bone stock, prior surgery and anticipated further surgery or surgeries. Prosthetic replacement is generally indicated for patients who have reached skeletal maturity.

Endoprostheses, unipolar and bipolar components are made of metal, polyethylene, or ceramic materials. The component material is identified on the outside carton label. All implantable devices are designed for single use only. Do not mix components from other manufacturers.

INDICATIONS

1. Non-inflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis;
2. rheumatoid arthritis;
3. arthritis secondary to a variety of diseases and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis;
4. revision procedures where other treatments have failed; and
5. treatment of proximal femoral non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement.

CONTRAINDICATIONS

1. Conditions that would eliminate or tend to eliminate adequate implant or cement support or both, or prevent the use of an appropriate size implant (except in a short life expectancy) as congenital dislocation of the hip, osteoporosis, and salvage procedures.
2. Previous infection; old osteomyelitis of the upper femur.
3. Mental conditions that preclude cooperation with the rehabilitation regimen.
4. Physical conditions or activities that place an extreme load on the implant(s). Included would be Charcot's joints, heavy labor, certain muscle deficiencies and multiple joint disabilities.
5. Skeletal immaturity.

WARNINGS

1. Care must be taken to assess the viability of the acetabular hyaline cartilage and the presence of any irregularity, anomaly, or surface configuration which may predispose to subluxation and/or dislocation of the prosthesis.
2. The available medical literature concerning the use of endoprostheses, unipolar and bipolar devices, should be carefully reviewed by the surgeon to ascertain whether any of the prostheses offer the best treatment option.
3. Loosening or fatigue of implants and other complications may result from failure to follow standard surgical technique or labeling, improper selection of instrumentation, or inappropriate patient selection.
4. Intraoperative fracture or instrument breakage can occur. Instruments which have been used extensively or with excessive force are susceptible to fracture. Examine all instruments for wear and damage prior to surgery. Replace where necessary.
5. Periodic x-rays are recommended for close comparison with immediate postoperative x-rays to detect long term evidence of changes in position, loosening, bending of components and/or bone loss. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of revision surgery be considered.
6. Closed reduction may not be possible for femoral head disassociation in bipolar components.

PRECAUTIONS

1. Use extreme care in handling and storing implant components. Cutting, bending, or scratching the surface can significantly reduce the strength, fatigue resistance and/or wear characteristics of the implant system.
2. Surgical technique information is available upon request. The surgeon should be familiar with the devices, instruments and surgical technique prior to surgery.
3. The correct selection of the implant is extremely important. The appropriate type and size should be selected for patients with consideration of anatomical and biomechanical factors, such as patient age and activity levels, pathology, weight, bone and muscle conditions. Failure to use the optimum size component may result in loosening, bending, cracking, or fracture of the component, cement or bone.
4. Correct selection of the neck length and stem positioning are extremely important. Muscle laxity and/or malpositioning of components may result in subluxation, dislocation, and/or fracture of the implants. Increased neck length and varus positioning will increase stresses on the stem.
5. Prior to closure, the surgical site should be thoroughly cleansed of bone chips, cement or other debris. Ectopic bone or bone spurs or both may lead to dislocation or painful or restricted motion. Range of motion should be thoroughly checked for abnormal implant contact or instability. Malpositioning of components can result in instability and dislocation.
6. Postoperative therapy should be structured to regain the patient's muscle strength around the hip and a gradual increase in activities.
7. Bipolar components that utilize a polyethylene liner are sensitive to extreme temperatures above 104° F (40° C) and below 32° F (0° C). Extreme temperatures may cause the polyethylene to expand/contract and compromise the fit of the liner into the shell or the head in the liner. In light of heat-sensitivity, unnecessary or prolonged handling of the component should be avoided.
8. Unipolar heads are designed to be used with 12/14 or large (14/16) taper sleeves. Consult catalog for size availability.

ADVERSE EFFECTS

1. Loosening, bending, cracking, or fracture of implant components have been reported.
2. Dislocations, subluxations, decreased range of motion, or lengthening or shortening of the femur, caused by improper neck selection, positioning, looseness of components or extraneous bone may occur. Penetration of the femoral prosthesis through the shaft of the femur, fracture of the acetabulum, especially with prior hip surgery and excessive reaming, have also been reported.
3. Fracture of the pelvis or femur is often caused by defects in the femoral cortex due to prior screw holes or misdirected reaming. Intraoperative fractures are usually associated with revision surgery, old congenital deformity and severe osteoporosis.
4. Acetabular pain and erosion have occurred when endoprostheses or unipolar and bipolar devices are used.
5. Infection, both acute postoperative wound infection and late deep sepsis, can occur.
6. Neuropathies of the femoral, sciatic, peroneal, and lateral femoral cutaneous nerves can occur.
7. Tissue reactions which include macrophage and foreign body reactions adjacent to implants, can occur.
8. Myositis ossificans is an adverse effect from hip arthroplasty. It can result in limited range of motion. The incidence is increased with prior surgery or presence of infection.
9. Wound hematoma and thromboembolic disease including venous thrombosis and pulmonary emboli, can occur following hip reconstruction.
10. Trochanteric nonunion, usually associated with early weight bearing or improper fixation of the trochanter, has been reported in the literature.
11. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials can occur.
12. Traumatic arthrosis of the knee can occur from intraoperative positioning of the extremity.
13. Aggravated problems of the affected limb or contralateral extremity can occur because of leg length discrepancy, excess femoral medialization, or muscle deficiency.

PACKAGING AND LABELING

Implants should be accepted only if received by the hospital or surgeon with the factory packaging and labeling intact. If the sterile barrier has been broken, refer to the "Sterilization/Resterilization" section below.

STERILIZATION/RESTERILIZATION

Most implants are supplied sterile and have been packaged in protective trays or pouches. The method of sterilization is noted on the package label. All radiation sterilized components have been exposed to a ninimum of 25 kiloGrays of gamma radiation. If not specifically labeled sterile, the implants and instruments are supplied non-sterile and must be sterilized prior to use. Inspect packages for punctures or other damage prior to surgery.

Metal Components

Metal components may be resterilized, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all original packaging and labeling. Protect the devices, particularly mating surfaces, from contact with metal or other hard objects which could damage the product. The following process parameters are recommended for these devices:

- Prevacuum Cycle: 4 pulses (Maximum = 26.0 psig (2.8 bars) & Minimum = 10.0 inHg (339 millibars)) with a minimum dwell time of 4 minutes at 270° F to 275° F (132° C to 135° C), followed by a 1 minute purge and at least 15 minutes of vacuum drying time.
- For the United Kingdom, sterilization should be carried out in accordance with HTM 2010. The recommended prevacuum sterilization cycle is: Evacuation to 100 mbar for 2-3 minutes, Negative Pressure pulsing (5): 800 mbar-100 mbar, Positive Pressure pulsing (5): 2.2 bar – 1.1 bar, Sterilization exposure: 3 minutes at 134°-137° C, Drying vacuum 40 mbar for 5-10 minutes. Note: mbar absolute.
- World Health Organization Steam Cycle: 4 pulses (Maximum – 26.0 psi, Minimum – 10.0 inHg (339 mbars)) with a minimum exposure time of 18 minutes at 134°C, followed by a 1 minute purge and at least 15 minutes of vacuum drying time.
- Gravity Cycle: 270° F to 275° F (132° C to 135° C) with a minimum dwell time at temperature of 15 minutes, followed by a 1 minute purge and at least 25 minutes of vacuum drying time.

Smith & Nephew does not recommend the use of low temperature gravity cycles or flash sterilization on implants.

Plastic Components

Plastic components may be resterilized by ethylene oxide gas. The following parameters are recommended as starting points for cycle validation by the health care facility:

Sterilant	Temp.	Humidity	Maximum Pressure	Concentration	Exposure Time
100% EtO	131° F (55° C)	40-80% (70% target)	10 PSIA (689 millibar)	725 mg/L	60-180 minutes

Suggested initial starting point for aeration validation is 12 hours at 120° F (49° C) with power aeration. Consult aerator manufacturer for more specific instructions.

Tandem Bipolar Implant

Iospital resterilization of the TANDEM™ Bipolar Shell and Liner is not recommended. Return the product to Smith & Nephew for resterilization.

Ceramic Components
Do not resterilize ceramic components.

INFORMATION
For further information, please contact Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

Manufacturing Facilities and EC Representative:

Smith & Nephew Inc., Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116 U.S.A.
Tel.: 901-396-2121

Smith & Nephew Orthopaedics GmbH
Alemannenstrasse 14
78532 Tuttlingen, Germany
Tel.: 07462/208-0
Fax: 07462/208-135

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

™Trademark of Smith & Nephew, Reg. U.S. Pat. & Tm. Off.

81007036 Rev. B 7/05 CE 0123

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

RECEIVED
FEB 15 1990

FEB 21 1990

REGULATORY AFFAIRS

Mr. Bob Games
Group Director-Regulatory Affairs
Smith and Nephew Richards Inc.
450 Brooks Road
Memphis, Tennessee 38116

Re: K896580
Uni-Polar Head
Regulatory Class: II
Dated: February 6, 1990
Received: February 8, 1990

Dear Mr. Games:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibition against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) 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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Carl A Larson

Carl A. Larson, Ph.D.
Director, Division of Surgical and
Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Premarket Notification Database

Device Classification Name	Prosthesis, Hip, Hemi-, Femoral, Metal
510(K) Number	K934353
Regulation Number	888.3360
Device Name	ZIRCONIUM ALLOY UNI-POLAR HEAD
Applicant	SMITH & NEPHEW RICHARDS, INC. 1450 E. Brooks Rd. Memphis, TN 38116
Contact	Thomas L Craig
Classification Product Code	KWL
Date Received	09/08/1993
Decision Date	04/25/1994
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary Only
Type	Traditional
Reviewed By Third Party	No

Database Updated 4/05/2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 25 1994

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

RECEIVED
MAY 2 1994
REGULATORY AFFAIRS

Mr. Thomas L. Craig
Director, Clinical and
Regulatory Affairs
Smith & Nephew Richards, Inc.
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K934353
Zirconium Alloy Uni-Polar Head
Regulatory Class: II
Dated: September 2, 1993
Received: September 8, 1993

Dear Mr. Craig:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and 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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being

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approved by FDA. If you desire specific advice on the labeling for your device, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

for Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Premarket Notification Database

Device Classification Name	Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented Or Uncemented
510(K) Number	K023743
Regulation Number	888.3390
Device Name	SMITH & NEPHEW GLOBAL BIPOLAR SYSTEM
Applicant	SMITH & NEPHEW, INC. 1450 Brooks Rd. Memphis, TN 38116
Contact	Janet Johnson Akil
Classification Product Code	KWY
Date Received	11/07/2002
Decision Date	01/23/2003
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Abbreviated
Reviewed By Third Party	No
Expedited Review	No

Database Updated 4/05/2006

13007.01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2003

JAN 2003
REGULATORY AND CLINICAL AFFAIRS

Ms. Janet J. Akil
Director, Regulatory Affairs
Orthopaedic Division
Smith & Nephew, Inc.
1450 Brooks Road.
Memphis, Tennessee 38116

Re: K023743
Trade Name: Global Bipolar System
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWY
Dated: November 6, 2002
Received: November 7, 2002

Dear Ms. Akil:

We have reviewed your Section 510(k) premarket 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) 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) 594-4659. 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 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 Mark N Melkerson

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

K023743

Global Bipolar System
Indications Statement

The Global Bipolar System is indicated for the following:

1. Non-inflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis;
2. rheumatoid arthritis;
3. arthritis secondary to a variety of diseases and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis;
4. revision procedures where other treatment or devices have failed; and
5. treatment of proximal femoral non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR (Per 21 CFR 801.109) Over-The Counter Use _____

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023743

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Pei Suiy

Subject: 510(k) Number K061243

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☒ YES	~~☒ NO~~

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☒ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 day

Predicate Product Code with class: KWL / II 8-336°

Additional Product Code(s) with panel (optional):

Review: Elizabeth Dee (Branch Chief) OJDB (Branch Code) 7/14/06 (Date)

Final Review: Barbara Bucchino (Division Director) 7/14/06 (Date)

Revised:4/2/03

Re: **K061243**
Trade/Device Name: Smith & Nephew Modular Femoral Head
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis,
Regulatory Class: Class II
Product Code: KWL
Dated: May 1, 2006
Received: May 3, 2006

PV 7/14/06 ELF 7/14/06

Recommendation:
This subject 510(k) notification:

- [x] is substantially equivalent to the marketed devices.
- [ ] requires more data.

Type letter and wording suggested:

BDB 7/14/06

- [x] "SE" Letter Attached
- [ ] "AI" Letter Attached
- [ ] "AI" via Telephone or Attached E-mail or Fax
- [ ] "NSE" Letter Attached

Summary:
The Smith & Nephew Modular Femoral Head is made of CoCr alloy, feature a 12/14 taper that mates with commercially available Smith & Nephew femoral stem is intended to be used for hemi-hip replacement articulating against the natural acetabulum.

Based on the similarities in intended use, device geometry and materials, and device characteristics to the listed predicates (i.e., K023743, K934353, and K896580) in the device comparison table (see 7/12/06, e-mail from S&N). "SE" is recommended.

The sponsor has adequately addressed all deficiencies.

Indications for Use: (Identical to K023743)
The modular heads are intended to be used as part of a hemi-hip replacement system when articulating against the natural acetabulum. The indications include:

- Noninflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis;
- rheumatoid arthritis;
- arthritis secondary to a variety of diseases and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis;
- revision procedures where other treatments have failed; and

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- treatment of proximal femoral non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement.

Device description:
The Smith & Nephew Modular Femoral Heads is made of CoCr alloy; feature a 12/14 taper and is intended to mate with commercially available Smith & Nephew femoral stems for hemi-hip applications.

Materials:
CoCrMo alloy (ASTM F-75 Standard)

The same material is used to manufacture hip components which have been cleared in premarket notifications listed below:

- Smith & Nephew Global Bipolar System, K023743
- Smith & Nephew Uni-Polar Head, K896580

Device dimension and geometry:
The diameter of the device is available in six sizes ranging from 38 to 58 mm, in 4mm increments. Each diameter size is offered with four offsets (i.e., -8, -4, +0, and +4mm).

A product list is provided in Exhibit "5". Two engineering drawings are included in Exhibit "4".

Device Testing and results:
b(4)Trade Secret Process - Testing

[redacted]

b(4)Trade Secret Process - Testing

[redacted]

Sterilization:
This device is intended to be provided sterile and will be sterilized by a minimum 2.5 Mrd gamma radiation and validated to SAL of [redacted] with an AMMI guideline for gamma sterilization.

No claim of "non-pyrogenic" is made. No pyrogen testing is conducted.

Description of the packaging used to maintain sterility is enclosed. Sterile notation reflects on the sample labeling.

The product is for single use only.

Labeling:
Representative draft samples of the labeling and insert are included in Exhibits 12 and 13.

Listed predicates:
Smith & Nephew Global Bipolar System, K023743
Smith & Nephew Uni-Polar Head, K896580
Smith & Nephew Zirconium Alloy Uni-Polar Head, K934353

A device comparison table has provided in 6/30/06 e-mail from S&N.

Brief Review of the Predicate Devices or Standards:
The function of the following 510(k)s are all indicated to articulate against the natural

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acetabulum.

K023743:
The Global Bipolar System consists of four components: a CoCr metal shell, a polyethylene bipolar liner, a polyethylene full lock ring liner, and a Ti6Al4V metal retaining ring. The CoCr metal shells range in size from 38-59mm, in 1mm increment.

K934353:
The size of this zirconium alloy unipolar head ranges from 38mm to 61mm in 1mm increment.

K896580:
This device consists of a modular unipolar sphere and a trunnion extension sleeve. The size is ranging from 47mm to 56mm. It is made of CoCr alloy.

Information Needed:

b(4)Trade Secret Process - Product Specs

[redacted]

b(4)Trade Secret Process - Product Specs

[redacted]

Conclusion:
This subject device is substantially equivalent to legally marketed devices, i.e., K023743, K934353, and K896580 in terms of device design, dimension, physical characteristics, and indications. The sponsor has adequately addressed all deficiencies.

Contact:
Mr. Gino J. Rouss
Regulatory Affairs Specialist
Smith & Nephew Orthopaedics
1450 E. Brooks Road
Memphis, TN 38116
Tel: (901) 399-6707
Fax: (901) 398-5146
Gino.rouss@smithnephew.com

Standards Data Form for Abbreviated 510(k)s

510(k) Number: K061243

Standard Organization: ASTM, ISO
Standard Identification No: F-75, 14630
CDRH Internal Reference No: Guidance for testing Acetabular Cup Prosthesis

Declaration of Conformity Elements:

Any Adaptations Applied	yes	x	no
Any Requirements Not Applicable	yes	x	no
Any Deviations Applied	yes	x	no
Any Differences in Device Tested and Finished Product	yes	x	no
Is There a Third Party or Test Lab Involved	yes	x	no

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Product to which compared: see review

		YES	NO	
1.	Is Product A Device	x		If NO = Stop
2.	Is Device Subject To 510(k)?	x		If NO = Stop
3.	Same Indication Statement?	x		If YES = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5.	Same Technological Characteristics?	x		If YES = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7.	Descriptive Characteristics Precise Enough?	x		If NO = Go To 10 If YES = Stop SE
8.	New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9.	Accepted Scientific Methods Exist?			If NO = Stop NE
10.	Performance Data Available?			If NO = Request Data
11.	Data Demonstrate Equivalence?			Final Decision:

Note: "Yes" responses to questions 4,6,8,11, and every "No" response requires an explanation.

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performances data are needed:
11. Explain how the performance data demonstrate that the device is or is not substantially equivalent:

Internal Administrative Form & Screening Checklist

	YES	NO
1. Did the firm request expedited review?		x
2. Did we grant expedited review?		x
3. Have you verified that the Document is labeled Class III for GMP purposes?	x	
4. If, not, has POS been notified?		
5. Is the product a device?	x	
6. Is the device exempt from 510(k) by regulation or policy?		x
7. Is the device subject to review by CDRH?	x	
8. Are you aware that this device has been the subject of a previous NSE decision?		x
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		x
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		

General information: required in all 510(k) submissions							
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	NA		YES		NO		
	Special		Abb.		T.		
	Yes	No	Yes	No	Yes	No	Missing
a) trade name, classification name, establishment registration number. device class			x				
b) or a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA		x				
d) compliance with Section 514 - performance standards	NA		x				
e) address of manufacturer			x				
f) Truthful and Accurate Statement			x				
g) Indications for Use enclosure			x				
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)			x				
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)							
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals			x				
k) Proposed Labeling:			x				
l) Comparison Information (similarities and differences) to namedlegally marketed equivalent device			x				
m) If kit, kit certification							
Abbreviated 510(K):							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. Should be included							
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards							
5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:			x				
b) Sterilization and expiration dating information:			x				
c) Software validation & verification:							

Passed Screening: Yes Reviewed by: Pei Sung Concurred by: ELF 7/14/06

13

From: Rouss, Gino [Gino.Rouss@smith-nephew.com]
Sent: Wednesday, July 12, 2006 1:27 PM
To: Sung, Pei
Subject: RE: K061243 - Smith & Nephew Modular Femoral Heads

b(4)Trade Secret Process - Product Specs

[redacted]

Best Regards,

Gino J. Rouss, MS
Regulatory Affairs Department
Orthopaedic Reconstruction
Smith & Nephew, Inc.

gino.rouss@smithnephew.com
T 901-399-6707
F 901-398-5146

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From: Rouss, Gino
Sent: Tuesday, July 11, 2006 2:48 PM
To: 'Sung, Pei'
Subject: RE: K061243 - Smith & Nephew Modular Femoral Heads

Dear Dr. Sung,

b(4)Trade Secret Process - Product Specs

[redacted]

Best Regards,

Gino J. Rouss, MS
Regulatory Affairs Department
Orthopaedic Reconstruction
Smith & Nephew, Inc.

gino.rouss@smithnephew.com
T 901-399-6707
F 901-398-5146

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From: Sung, Pei [mailto:pei.sung@fda.hhs.gov]

14

Sent: Friday, July 07, 2006 12:22 PM
To: Rouss, Gino
Subject: RE: K061243 - Smith & Nephew Modular Femoral Heads

Gino:

b(4)Trade Secret Process - Product Specs

[redacted]

Thank you,

Pei

From: Rouss, Gino [mailto:Gino.Rouss@smith-nephew.com]
Sent: Friday, June 30, 2006 8:37 AM
To: Sung, Pei
Subject: K061243 - Smith & Nephew Modular Femoral Heads

Dear Dr. Sung,

b(4)Trade Secret Process - Product Specs

[redacted]

Best Regards,

Gino J. Rouss, MS
Regulatory Affairs Department
Orthopaedic Reconstruction
Smith & Nephew, Inc.

gino.rouss@smithnephew.com
T 901-399-6707
F 901-398-5146

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Smith & Nephew Modular Femoral Heads
Design Comparison Table

[redacted]

b(4)Trade Secret Process - Product Specs

b(4)

Orthopaedics
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

T 901-399-5721
F 901-399-6990
www.smith-nephew.com

We are smith&nephew

To	Gino Rouss
From	Wayne Allen
Date	July 14, 2006
Subject	[redacted] b(4)Trade Secret [redacted]

b(4)Trade Secret Process - Product Specs

[redacted]

Memo

Sung, Pei

From: Rouss, Gino [Gino.Rouss@smith-nephew.com]
Sent: Tuesday, July 11, 2006 3:48 PM
To: Sung, Pei
Subject: RE: K061243 - Smith & Nephew Modular Femoral Heads
Attachments: Memorandum-K061243.pdf

Dear Dr. Sung,

b(4)Trade Secret Process - Product Specs

[redacted]

Best Regards,

Gino J. Rouss, MS
Regulatory Affairs Department
Orthopaedic Reconstruction
Smith & Nephew, inc.

gino.rouss@smithnephew.com
T 901-399-6707
F 901-398-5146

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From: Sung, Pei [mailto:pei.sung@fda.hhs.gov]
Sent: Friday, July 07, 2006 12:22 PM
To: Rouss, Gino
Subject: RE: K061243 - Smith & Nephew Modular Femoral Heads

Gino:

b(4)Trade Secret Process - Product Specs

[redacted]

Thank you,

Pei

From: Rouss, Gino [mailto:Gino.Rouss@smith-nephew.com]
Sent: Friday, June 30, 2006 8:37 AM
To: Sung, Pei
Subject: K061243 - Smith & Nephew Modular Femoral Heads

Dear Dr. Sung,

b(4)Trade Secret Process - Product Specs

[redacted]

b(4)Trade Secret Process - Product Specs

[redacted]

Best Regards,

Gino J. Rouss, MS
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7/11/2006

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To	Gino Rouss
From	Wayne Allen
Date	July 11, 2006
Subject	Follow-up to Memorandum April 27, 2006

(b) (4)

[redacted]

(b) (4)

[redacted]

Memo

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Exhibit 1

Greene, Walter B. and Heckman, James D. *The Clinical Measurement of Joint Motion,* (1st Edition) Illinois: American Academy of Orthopaedic Surgeons, 1994.

CHAPTER 11

The Hip

The hip is a ball and socket joint capable of considerable triaxial motion. The acetabulum, in comparison to the glenoid, is considerably deeper and, therefore, the range of hip motion is considerably less than the shoulder, the other ball and socket joint.

Normal range of hip motion at different ages is listed in Table 11.1. The data included in this table are from studies that measured hip motion using methods described in this chapter.

Hip motion is strikingly different in newborn children. Many studies have confirmed that neonates have a significant hip flexion contracture that averaged 28° in the study by Haas and associates,[79] 30° in the study by Forero and associates,[26] 46° in the study by Waugh and associates,[80] and ranged from 50° to 80° in the report by Hoffer.[27] Neonates have more external rotation than internal rotation.[23,26,79] The total arc of hip rotation is also increased, averaging 171° in neonates[26] compared with the 90° to 100° arc of rotation normally seen in children older than one year of age. Because rotation is greater with the hip in flexion, the increased range of hip rotation in neonates may be secondary to their associated flexion contracture.

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Exhibit 1 continued

Table 11.1

HIP MOTION AT DIFFERENT AGES (IN DEGREES)

	Neonate[26] Mean±s.d.	4 Year[19] Mean±2s.d.	8 Year[19] Mean±2s.d.	11 Year[19] Mean±2s.d.	Adult[14] Mean±s.d.	Adult[24] Mean±s.d.	Adult[18] Mean±s.d.
Extension	minus 30±3.9	29±6.3	27±6.3	25±14.0	12±5.4	19±8	9± 5.2
Flexion	128±4.8	150±12.5	146±11.3	138±14.5	121±6.4	121±13	120±8.3
Abduction	79*±4.3	54±9.0	49±7.3	45±10.8	41±6.0	42±11	39±7.2
Adduction	17±3.5	30±5.0	28±6.0	29±6.3	27±3.6	—	31±7.3
Internal Rotation	76±5.6	55±17.8	54±17.5	48±16.0	44±4.3	32±8	33±8.2
External Rotation	92±3.0	46±16.8	43±17.5	42±15.3	44±4.8	32±9	34±6.8

* Measured in flexion. Other studies in adults and older children measured abduction with hip extended (in neutral).

Memo

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Exhibit 2

The following highlighted excerpt and table of normal hip joint ranges of motion are from a book published by the AAOS:

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14. Boone DC, Azen SP: Normal range of motion of joints in male subjects. *J Bone Joint Surg* 1979; 61A:756-9.
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19. Svenningsen S, Terjesen T, Auflem M, et al: Hip motion related to age and sex. *Acta Orhtop Scand* 1989; 60:97-100.
24. Roach KE, Miles TP: Normal hip and knee active range of motion: The relationship to age. *Phys Ther* 1991; 71:656-65.

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Exhibit 3

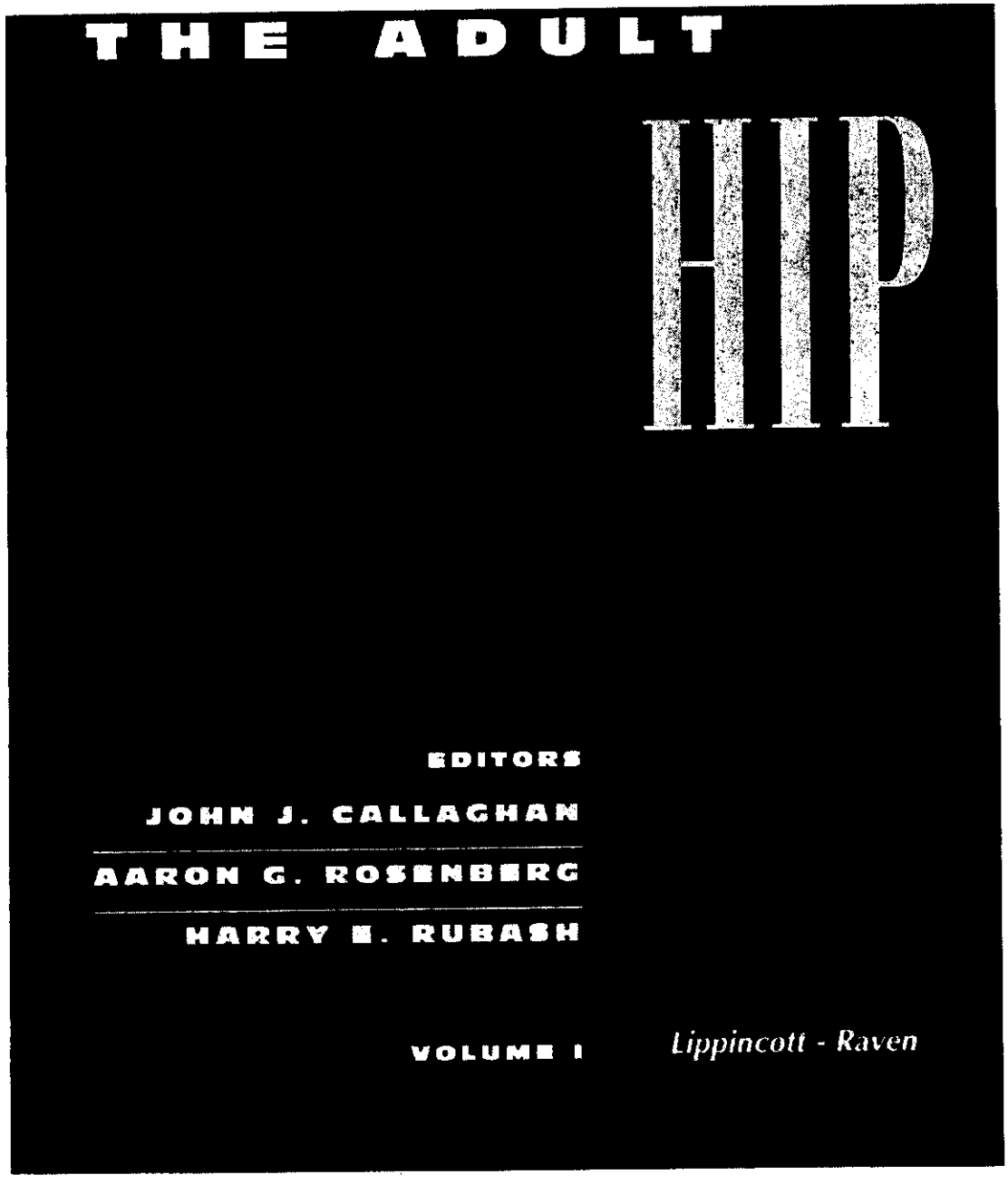

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Exhibit 4 (Note last sentence in the first Paragraph under Hip Joint Musculature)

the joint and the position of maximum stability (125). Interestingly, in full extension the articular surfaces of the joint are not in optimal contact. The position of optimal articular contact (flexion, abduction, and external rotation) is the loose-packed position, because flexion and lateral rotation tend to uncoil the ligaments. Because the joint surfaces are neither maximally congruent nor close-packed, the hip joint is at greatest risk for traumatic dislocation when flexed and adducted (21,52).

HIP JOINT MUSCULATURE

The muscles of the hip joint operate as part of a closed kinematic chain-link system. The muscles are unique in their large areas of origin and insertion (Fig. 4), their length, and their large cross section. These characteristics, in combination with the large range of motion available at the hip joint, result in muscle function that is dependent on limb position (Table 1). The range of motion accommodated at the hip is flexion 120°, extension 30°, abduction 45° to 50°, adduction 20° to 30°, internal rotation 35°, and external rotation 45° (40,78). Normal gait on level ground requires at least the following hip joint ranges of motion: 30° flexion, 10° hyperextension, 5° of both abduction and adduction, and 5° of both internal and external rotation (48). Walking on uneven terrain or stairs will increase the need for joint range beyond that required for level ground, as will activities such as sitting in a chair or sitting cross-legged. Pain relief is the predominant reason for joint replacement surgery, but an understanding of the surrounding muscles can help the surgeon restore their function (11, 14,69,84,89).

Flexors

The primary hip flexors are the iliopsoas, rectus femoris, and sartorius. The iliopsoas muscle consists of two separate muscles, the iliacus muscle and the psoas major muscle, which converge together into a common tendon to insert onto the lesser trochanter of the femur. The iliopsoas muscle has a broad origin including the iliac crest and fossa, sacral ala and iliolumbar and sacroiliac ligaments (the iliac contribution), and sides of the

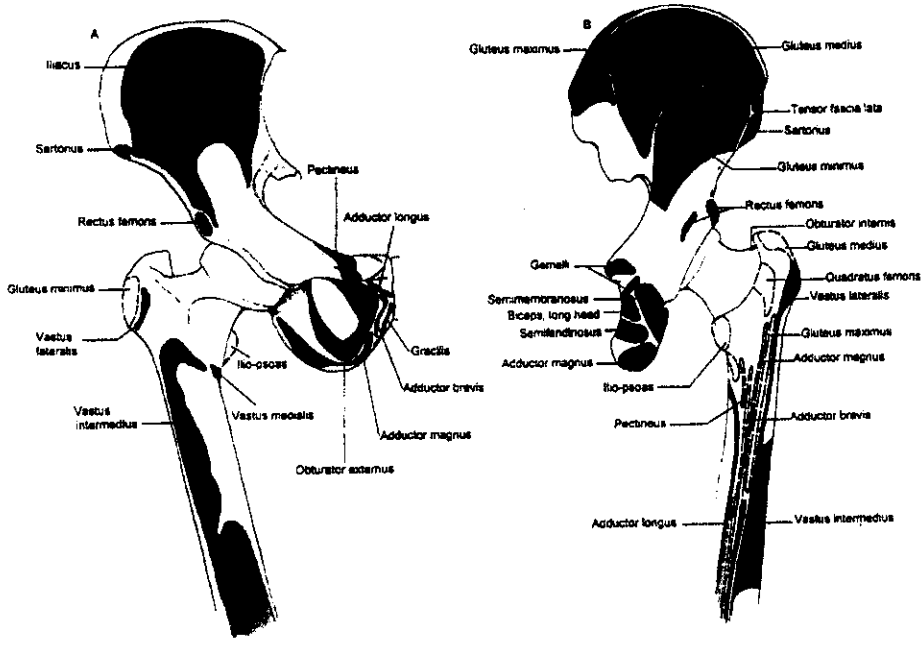

FIG. 4. A: Schematic diagram of the intrapelvic view of the pelvic bone and proximal femur, demonstrating the muscle origins and insertions. B: Schematic diagram of the extrapelvic view of the pelvic bone and proximal femur, demonstrating the muscle origins and insertions.

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Sung, Pei

From: Rouss, Gino [Gino.Rouss@smith-nephew.com]
Sent: Friday, June 30, 2006 8:37 AM
To: Sung, Pei
Subject: K061243 - Smith & Nephew Modular Femoral Heads
Attachments: Normal Hip Joint Range of Motion.doc; smith and nephew modular head rom.doc; Design Comparison Table.doc

Dear Dr. Sung,

(b) (4)

[redacted]

Best Regards,

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To	Gino Rouss, Regulatory Affairs Specialist
From	Wayne Allen, Product Development MGR.
Date	June 29, 2006
Subject	ROM for Smith and Nephew Modular Head

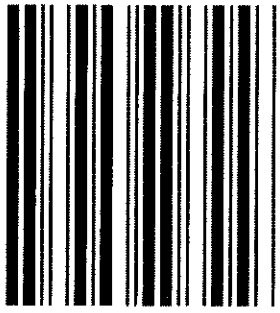
b(4)Trade Secret Process - Product Specs

[redacted]

Memo

29

[1]Green, Walter B. and Heckman, James D. *The Clinical Measurement of Joint Motion* (1st Edition) Illinois: American Academy of Orthopaedic Surgeons, 1994

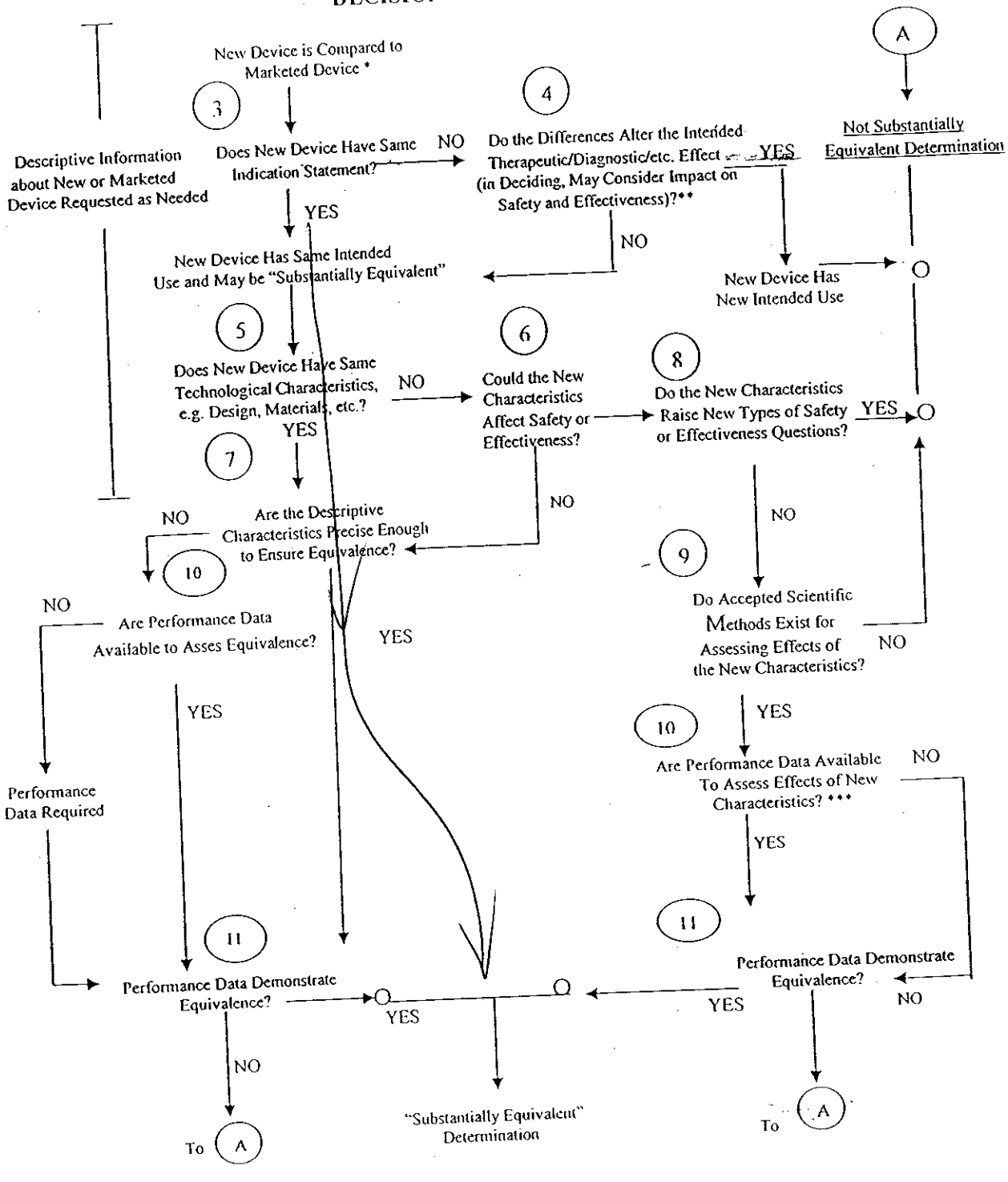


Smith & Nephew Modular Femoral Heads
Design Comparison Table

b(4)Trade Secret Process - Product Specs

[redacted]

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.