



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (kml)
FOLDER: K062408 - 67 pages
COMPANY: SMITH & NEPHEW, INC. (SMITNEPH)
PRODUCT: PROSTHESIS, HIP, HEMI-, FEMORAL, METAL (KWL)
SUMMARY: Product: SMITH & NEPHEW MODULAR FEMORAL (HEMI) HEAD

DATE REQUESTED: Jan 4, 2016

DATE PRINTED: Jan 4, 2016

Note: Printed



K062408 (p 1 of 1)

510(K) Summary
Smith & Nephew Modular Femoral (Hemi) Heads

SEP 12 2006

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: August 15, 2006
TRADE OR PROPRIETARY DEVICE NAME: Smith & Nephew Modular Femoral (Hemi) 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 female Morse-type taper that has been modified to accept taper sleeves that create a variety of neck length offsets. The taper sleeves feature a 12/14 female taper for attachment to the trunnion of a commercially-available Smith & Nephew femoral stem. The overall design of the component is based upon the existing Smith & Nephew Modular Heads and Uni-polar implants subject of K061243 and K896580, respectively.

C. SUBSTANTIAL EQUIVALENCE INFORMATION:

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

- Smith & Nephew Modular Femoral Heads (K061243)
- Smith & Nephew Uni-Polar Head (K896580)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2006

Smith & Nephew Orthopaedics
c/o Mr. Gino J. Rouss
Project Manager, Regulatory Affairs
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K062408

Trade/Device Name: Smith & Nephew Modular Femoral (Hemi) Heads
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: August 15, 2006
Received: August 17, 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.

Page 2 – Mr. Gino J. Rouss

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,

A handwritten signature in black ink, appearing to read "Barbara P..." with a small "for" written below the name.

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): K062408

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;
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- 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.

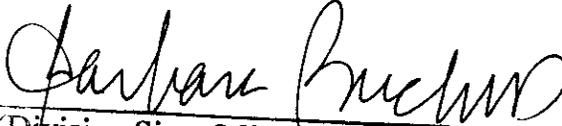
Prescription Use X
(Part 21 CFR 801 Subpart D)

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)


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

Page 1 of _____

510(k) Number 1x062408



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2006

Smith & Nephew Orthopaedics
c/o Mr. Gino J. Rouss
Project Manager, Regulatory Affairs
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K062408

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Page 2 – Mr. Gino J. Rouss

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Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a small "for" written below the main name.

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): K062408

Device Name: Smith & Nephew Modular Femoral Heads

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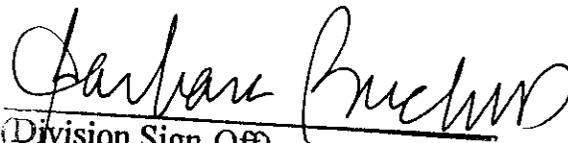
Prescription Use X
(Part 21 CFR 801 Subpart D)

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)



(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K062408

Page 1 of _____

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

August 18, 2006

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

510(k) Number: K062408
Received: 17-AUG-2006
Product: SMITH & NEPHEW
MODULAR FEMORAL
(HEMI) HEAD

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) 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.

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 510(k) submission.

Please note the following documents as they relate to 510(k) review:
1) 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 (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html.
2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at 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).
3) 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.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRHs e-Copy Program, you may replace one paper copy of an premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsb.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (301)594-1190.

Sincerely yours,

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

August 17, 2006

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

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

510(k) Number: K062408
Received: 17-AUG-2006
Product: SMITH & NEPHEW
User Fee ID Number: 6027022RAL
(HEMI) 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 all future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail

Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733.

By Private Courier (e.g., Fed Ex, UPS, etc.)

U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101
(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/oc/mdufma.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/electsub.html.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-free number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Christina Zeender at 301-827-2860. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b) (4) 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: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR)		3.1 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> 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.			
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> 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).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005) (b) (4)			

(Close Window)

K2714
OR
II

August 15, 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 (Hemi) Head: Special 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 (Hemi) Heads.

Smith & Nephew is submitting this Special 510(k) in accordance with *The New 510(k) Paradigm: Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications*, dated March 20, 1998. It is our belief that the device subject of this submission is eligible for review under the Special 510(k) process given that it shares the same fundamental scientific technology, intended use, and are manufactured from the same material as currently marketed devices.

Per the requirements of a Special 510(k) filing, the following information is included:

- Items required under § 807.87, including a description of the modified device and a comparison to the cleared device, the intended use of the device, and the proposed labeling for the device;
- A concise summary of the design control activities;
- A Declaration of Conformity with Design Controls; and
- Indications for Use enclosure.

We consider our intent to market these devices to be confidential commercial information, and therefore exempt from public disclosure. We have taken precautions to protect confidentiality of the intent to market these devices.

We believe this information fulfills the requirements for the present Special 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 J. Rouss, MS

Project Manager – Regulatory Affairs
Smith & Nephew Orthopaedics

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission: 08/15/2006
User Fee Payment ID Number: (b) (4)
FDA Submission Document Number (if known):

SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission Amendment Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission Amendment Supplement Report Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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 Project Manager - Regulatory Affairs		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	

510(K) ROUTE SLIP
SPECIAL

510(k) NUMBER: K062408 PANEL: OR DIVISION: DGRND BRANCH:
ELECTRONIC SUBMISSION: N

TRADE NAME: SMITH & NEPHEW MODULAR FEMORAL (HEMI) HEAD

COMMON NAME: ARTIFICIAL HIP REPLACEMENT PROSTHESIS

PRODUCT CODE: _____

APPLICANT: SMITH & NEPHEW, INC.

SHORT NAME: SMITNEPH

CONTACT: GINO ROUSS

DIVISION: ORTHOPAEDIC DIVISION

ADDRESS: 1450 BROOKS RD.
MEMPHIS, TN 38116

PHONE NO. (901) 399-6707

FAX NO. (901) 398-5146

MANUFACTURER: SMITH & NEPHEW, INC.

SMITH & NEPHEW ORTHOPEADICS LT
SWANN MORTON, LTD.

REG NO. 1020279

9611194

DATE ON SUBMISSION: 15-AUG-2006

DATE DUE POS: 11-SEP-2006

DATE RECEIVED IN ODE: 17-AUG-2006

DATE DECISION DUE: 16-SEP-2006

DECISION: ___

DECISION DATE: _____

Is this 510(k) identified as a Class III device ___ YES ___ NO
Is this 510(k) the result of additional information ___ YES ___ NO

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

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

- Location change:
 - Manufacturer
 - Sterilizer
 - Packager

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

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

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

- Response to FDA correspondence:

- 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

- 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

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

- Other Reason (*specify*):

SECTION D3

REASON FOR SUBMISSION - 510(k)

- New Device

- Additional or Expanded Indications

- Change in Technology

- Other Reason (*specify*):

Modification to Existing Device already cleared for market under premarket notification 510(k) K061243.

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

- 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	K061243	Modular Femoral Heads	Smith & Nephew, Inc.
2	K896580	Uni-Polar Femoral Heads	Smith & Nephew, Inc.
3	K023743	Global Bipolar System	Smith & Nephew, Inc.
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Hip Joint Femoral (hemi-hip) metallic cemented or uncemented prosthesis, 21 CFR 888.3360 - Class II

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

- Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code KWL	C.F.R. Section (if applicable) 21 CFR 888.3360	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> 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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number 1020279		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> 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 Brocks 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 Project Manager - Regulatory Affairs		Contact E-mail Address gino.rouss@smithnephew.com	

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number n/a - Currently Registering Facility		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Smith & Nephew Orthopaedics Limited			Establishment Registration Number n/a - Currently Registering Facility		
Division Name (if applicable) Orthopaedics			Phone Number (including area code) (901) 399-6670		
Street Address 1 Kingmaker Court - Warwick Technology Park			FAX Number (including area code) (901) 398-5146		
City Warwick		State / Province	ZIP/Postal Code CV34 6WG	Country UK	
Contact Name John Reabe		Contact Title Director - Regulatory Affairs		Contact E-mail Address john.reabe@smithnephew.com	

b(4)Trade Secret Process - Product Specs



20

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 Spec. for Cobalt-28 Chromium-6 Molybdenum /		12/10/2001
2	14630	ISO	Non-Active Surgical Implants - General Requirements		02/19/1998
3	F1537	ASTM	Standard Spec. for Cobalt-28 Chromium-6 Molybdenum /		05/10/2000
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

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

Smith & Nephew Modular Femoral (Hemi) Head

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Manufacturer's Name	
Establishment Registration Number	
Primary and Secondary Contact	
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Proprietary Name	
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Device Classification for the Predicate Device	
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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 Special 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 with Design Controls is provided as **Exhibit 3**. The Declaration of Conformity includes the following information:

- A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met; and
- A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

The above two statements have been signed by the individual(s) responsible for those particular activities.

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
Project Manager – Regulatory Affairs
Smith & Nephew Orthopaedics
Tel: (901) 399-6707
Fax: (901) 398-5146

Secondary Contact Person: Jason Sells
Project Manager – Regulatory Affairs
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
1 Kingmaker Court
Warwick Technology Park
Gallows Hill
Warwick
CV34 6WG United Kingdom

II. DEVICE INFORMATION

A. Intended Use

The Smith & Nephew Modular Femoral (Hemi) Heads feature a female Morse-type taper that mates with taper extension sleeves that provide various neck length adjustments. The taper sleeves contain a 12/14 taper and are designed to be used 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 the currently marketed Smith & Nephew hip device listed below.

Table I: Predicate Device with identical Indications for Use

Description	Submission Number	Clearance Date
Modular Femoral Heads	K061243	07/17/06

B. Device Description

Subject of this premarket notification are cobalt chrome (CoCr) modular femoral (hemi) heads that are offered in sizes ranging from 38-58mm. The overall design of the modular femoral heads is based on the existing femoral head components cleared via 510(k) premarket notification K061243. The newly designed modular femoral heads feature a female Morse-type taper that has been modified to accept taper sleeves that create neck length offsets of -4, +0, +4, and +8mm.

Each of the components is described below and on the following pages.

Modular Femoral (Hemi) Head Components:

The modular femoral heads are offered in sizes ranging from 38-58mm. The components are cast from cobalt chrome (CoCr) alloy and feature a female Morse-type taper interface that mates with wrought cobalt chrome (CoCr) taper sleeves.

Taper Sleeve Components:

The taper sleeve components feature an external taper for attachment of the modular femoral (hemi) head component, and a 12/14 female taper for attachment to the trunnion of a commercially-available Smith & Nephew femoral stem. Both tapers on the taper sleeve component are intended to provide for a mechanically-locked fit against the respective modular head and femoral stem components. The taper sleeves are manufactured from wrought cobalt chrome (CoCr) and include neck length offset adjustments of -4, +0, +4, and +8mm. The taper sleeve design is identical to that used on existing Smith & Nephew Uni-Polar Femoral Head components cleared for market under 510(k) K896580.

In keeping with the design philosophy of the predicate Smith & Nephew Modular Femoral Head components, the femoral (hemi) heads are intended to be used as part of a hemi-hip replacement system when articulating against the natural acetabulum. The modular heads and taper sleeves are compatible with existing Smith & Nephew femoral stem 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 (hemi) head and taper sleeve is provided in **Exhibit 4**. A component description list is provided in **Exhibit 5**. A **Device Comparison Table** has been provided in **Exhibit 6** to summarize the device features of the newly designed Smith & Nephew modular femoral heads compared with the devices cleared for market under 510(k) premarket notifications K061243 and K896580.

C. Materials

The Smith & Nephew modular femoral (hemi) 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:

Table III: Predicate Knee Systems Containing the Same Material

Description	Submission Number	Clearance Date
Modular Femoral Heads	K061243	07/17/06
Uni-Polar Head	K896580	02/15/90

The taper sleeves will be manufactured from Cobalt-Chromium-Molybdenum Alloy (Co-Cr-Mo) material conforming to:

ASTM F 1537 Standard Specification for Wrought Cobalt – 28Chromium – 6Molybdenum Alloys for Surgical Implant Applications

ISO 5832 Implants for Surgery – Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications

D. Sterilization Information

The Smith & Nephew Modular Femoral (Hemi) Heads and Taper Sleeves 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 7**.

E. Labeling

Carton labels for the Smith & Nephew Modular Femoral (Hemi) Heads are provided in **Exhibit 8**. 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 (Hemi) Head components is provided in **Exhibit 9**. A draft surgical technique for the subject device is included in **Exhibit 10**.

F. Software

This section does not apply.

G. Electromagnetic Compatibility and Electrical Safety

This section does not apply.

H. Design Control Activities Summary

According to the Guidance Document, *The New 510(k) Paradigm: Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications*, appropriate Design Control Activities have been completed for the subject Smith & Nephew Modular Femoral (Hemi) Head components. The risk analysis used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA). The design verification tests that were performed as a result of this risk analysis assessment are listed in **Exhibit 11**.

These design verification tests are based on requirements outlined in FDA's *Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Testing Acetabular Cup Prosthesis*, dated May 1995.

As required in the guidance document, the concise summary of the design activities includes the following information:

- An identification of the Risk Analysis method(s) used to assess the impact of the modification on the device and its components as well as the results of the analysis; and
- Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and the acceptance criteria applied.

I. Substantial Equivalence Information

The overall designs and the indications for use for the Smith & Nephew Modular Femoral (Hemi) Heads are substantially equivalent to previously cleared devices listed below.

Table IV: Predicate Hip Devices

Manufacturer	Description	510(K)	Clearance Date
Smith & Nephew, Inc.	Modular Femoral Heads	K061243	07/17/06
Smith & Nephew, Inc.	Uni-Polar Head	K896580	02/15/90

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

Table V: Predicate Hip Systems Containing the Same Material

Manufacturer	Description	510(K)	Clearance Date
Smith & Nephew, Inc.	Modular Femoral Heads	K061243	07/17/06
Smith & Nephew, Inc.	Global Bipolar System	K023743	01/23/03
Smith & Nephew, Inc.	Uni-Polar Head	K896580	02/15/90

Premarket notification information for predicate devices is located in **Exhibit 12**.

In summary, the Smith & Nephew Modular Femoral (Hemi) 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.

Smith & Nephew Modular Femoral (Hemi) 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 with Design Controls |
| Exhibit 4 | Representative Engineering Drawings |
| Exhibit 5 | Component Descriptions |
| Exhibit 6 | Device Comparison Table |
| Exhibit 7 | Sterilization Information |
| Exhibit 8 | Sample Carton Labels |
| Exhibit 9 | Package Insert |
| Exhibit 10 | Draft Surgical Technique |
| Exhibit 11 | Design Control Activities Summary |
| Exhibit 12 | Predicate Device Information |

TRUTHFUL AND ACCURATE STATEMENT

I certify that, in my capacity as a Project Manager in Regulatory Affairs 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: 08/15/06

510(K) Summary
Smith & Nephew Modular Femoral (Hemi) 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: August 15, 2006
TRADE OR PROPRIETARY DEVICE NAME: Smith & Nephew Modular Femoral (Hemi) 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 female Morse-type taper that has been modified to accept taper sleeves that create a variety of neck length offsets. The taper sleeves feature a 12/14 female taper for attachment to the trunnion of a commercially-available Smith & Nephew femoral stem. The overall design of the component is based upon the existing Smith & Nephew Modular Heads and Uni-polar implants subject of K061243 and K896580, respectively.

C. SUBSTANTIAL EQUIVALENCE INFORMATION:

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

- Smith & Nephew Modular Femoral Heads (K061243)
- Smith & Nephew Uni-Polar Head (K896580)

SPECIAL PREMARKET NOTIFICATION
Smith & Nephew Modular Femoral (Hemi) Head

Declaration of Conformity with Design Controls

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined criteria were met.

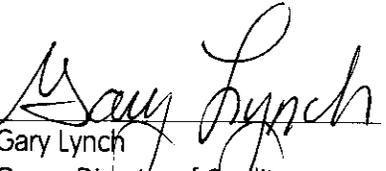


Gary Lynch
Group Director of Quality
Smith & Nephew, Inc.

8/15/06

Date

The manufacturing facility, Smith & Nephew, Inc., is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.



Gary Lynch
Group Director of Quality
Smith & Nephew, Inc.

8/15/06

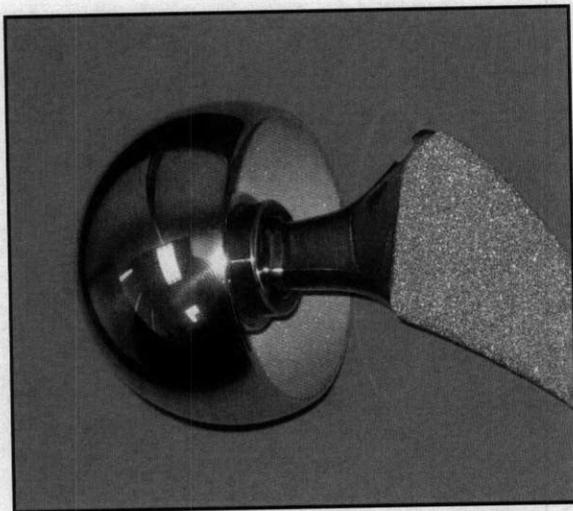
Date

Smith & Nephew Modular Femoral (Hemi) Head

Product Descriptions

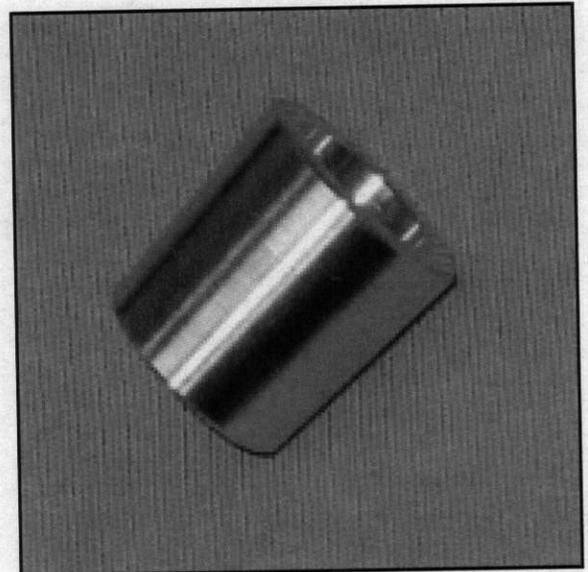
Modular Femoral Heads
Modular (Hemi) Head 38mm
Modular (Hemi) Head 40mm
Modular (Hemi) Head 42mm
Modular (Hemi) Head 44mm
Modular (Hemi) Head 46mm
Modular (Hemi) Head 48mm
Modular (Hemi) Head 50mm
Modular (Hemi) Head 52mm
Modular (Hemi) Head 54mm
Modular (Hemi) Head 56mm
Modular (Hemi) Head 58mm

Taper Sleeves
12/14 Modular Taper Sleeve (-4mm)
12/14 Modular Taper Sleeve (+0mm)
12/14 Modular Taper Sleeve (+4mm)
12/14 Modular Taper Sleeve (+8mm)



Modular (Hemi) Head / Taper Sleeve / Femoral Stem

Taper Sleeve



Device Comparison Table

Comparison	Subject Device Smith & Nephew Modular Femoral Heads (Hemi)	Predicate Device Smith & Nephew Modular Femoral Heads (Hemi) – K061243
Indications for Use	<p>The Smith & Nephew Modular Femoral Heads are indicated for the following:</p> <ul style="list-style-type: none"> • 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. <p>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.</p>	<p>The Smith & Nephew Modular Femoral Heads are indicated for the following:</p> <ul style="list-style-type: none"> • 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. <p>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.</p>

Device Comparison Table

Comparison	Subject Device Smith & Nephew Modular Femoral Heads (Hemij)	Predicate Device Smith & Nephew Modular Femoral Heads (Hemij) – K061243	Predicate Device Smith & Nephew Uni-Polar Femoral Heads – K896580
Device Design	<ul style="list-style-type: none"> - Modular Taper Connection - Size Range: 38-58 mm - Taper Sleeves allow use with 12/14 Stems - -4, +0, +4, or +8mm neck lengths - Material: CoCr 	<ul style="list-style-type: none"> - Modular with 12/14 Taper - Size Range: 38-58 mm - -8, -4, +0, or +4mm neck lengths - Material: CoCr 	<ul style="list-style-type: none"> - Modular Taper Connection - Taper Sleeves allow use with 12/14 Stems - Size Range: 38-61mm - Material: CoCr

Radiation Sterilization Process

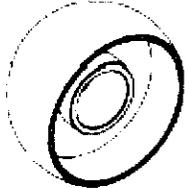
Source/Type of Sterilization:	Cobalt 60/Gamma radiation
Sterility Assurance Level:	(b) (4)
Type of Cycle:	Overkill
Dosage:	25 Kilo grays minimum
Validation:	Validation is accomplished by following the procedures set forth by the Association for the Advancement of Medical Instrumentation (AAMI) Guideline 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 (Hemi) Heads
Sample Outer Carton Label – Modular Femoral Head

REF 74122538 QTY: (1) 

MODULAR FEMORAL HEAD

TETE FEMORALE / HÜFTKOPF
CABEZA FEMORAL / TESTA FEMORALE



38MM

LOT NO. SAMPLE

HEMI-ARTHROPLASTY USE ONLY

USE ONLY WITH MODULAR HEAD SLEEVE

CO-CR

MADE IN UNITED KINGDOM

LOT SAMPLE

CE 0120

STERILE R

2011/08



Smith & Nephew Orthopaedics
Ltd Warwick United Kingdom CV34
6WG



~H435741225381H



~\$SAMPLEH2

1401 644

Smith & Nephew Modular Femoral (Hemi) Heads

Sample Outer Carton Label - Taper Sleeve

REF 74223100 QTY: (1) 

MODULAR HEAD
SLEEVE
GAINE / HULSE
MANGUITO / MANICOTTO



-4 MM

LOT NO. SAMPLE

USE ONLY WITH
MODULAR FEMORAL HEAD



MADE IN UNITED KINGDOM

CO-CR

 SAMPLE

 0120

 STERILE  R

 2011/08

Smith & Nephew Orthopaedics,
Ltd. Warwick, United Kingdom
CV34 6WG

ZIVTAC

Endoprosthesis 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.

Endoprosthesis, 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 endoprosthesis, 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. 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 minimum 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

Hospital 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

Smith & Nephew Orthopaedics Limited
1 Kingmaker Court
Warwick Technology Park
Gallows Hill
Warwick CV34 6WG
United Kingdom
Tel.: 44 (0) 1926 482400



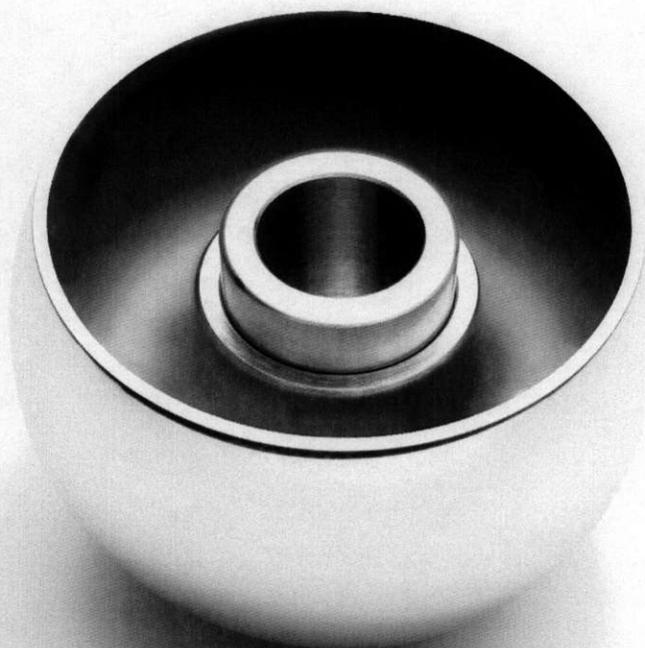
Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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

81007036

Modular Head
Hemi-Arthroplasty System

DRAFT



DRAFT

Introduction

The Modular heads shown are compatible with any of the femoral stem range from Smith & Nephew.

Following implantation of the chosen stem, the appropriately sized modular head should be attached as shown in the following assembly guide.



Sleeved Modular Head System

Surgical Technique

Implant Assembly

Clean and dry the stem taper. Firmly place the appropriate taper sleeve on the femoral taper (Figure 1).

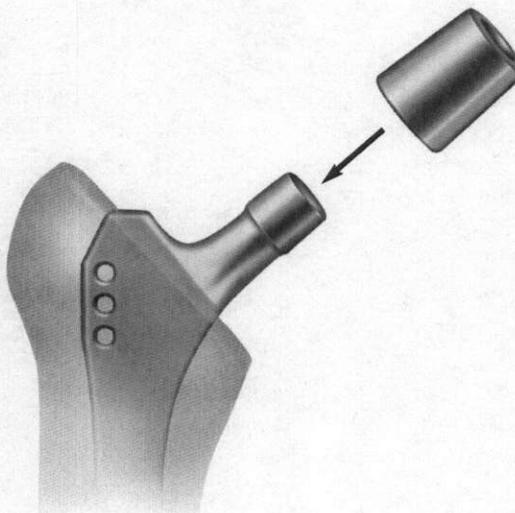


Figure 1

Clean and dry the taper sleeve and place the appropriate size modular head onto the sleeve (Figure 2).

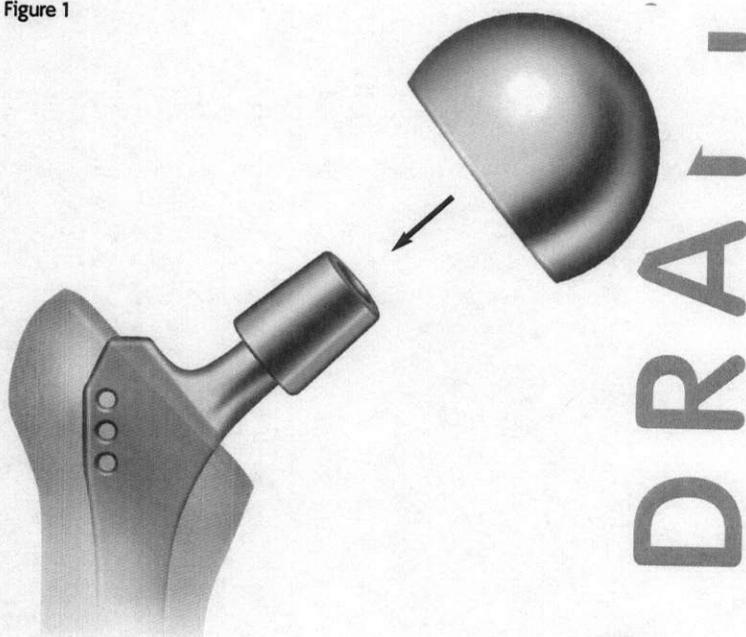


Figure 2

Impact with the femoral head impactor and mallet (Figure 3).

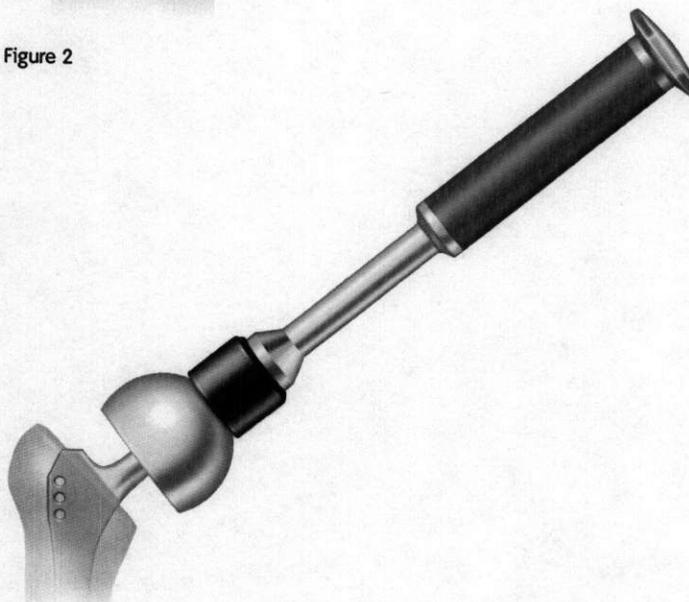


Figure 3

DRAI!

DRAFT

Implant Disassembly

After removing the modular head from the taper sleeve, attach the Sleeve Remover Tool around the base of the sleeve implant. Turn the T-Bar clockwise until the sleeve separates from the stem (Figure 4).

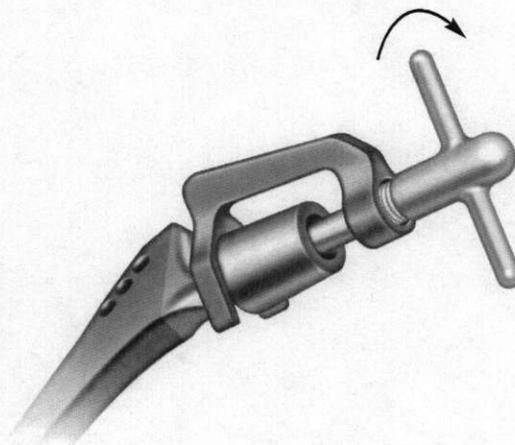


Figure 4

To remove the taper sleeve from the modular head, insert the Head Separator Device into the sleeve until it reaches the inside of the head, ensuring that the two guide marks are aligned during insertion (Figure 5).

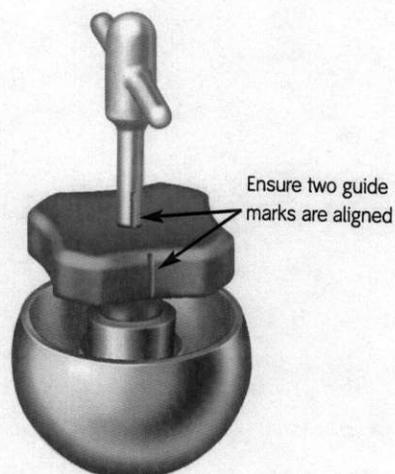


Figure 5

Turn the T-Bar clockwise to release the sleeve from the modular head (Figure 6).

NOTE: Please ensure that the head does not make contact with any metal instruments as surface damage may occur.

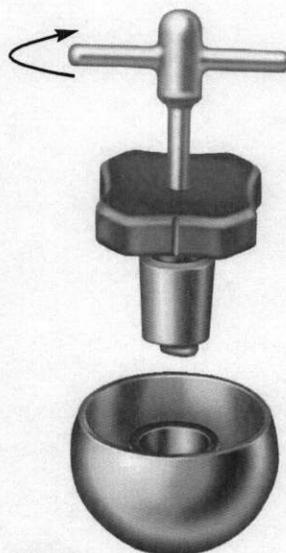


Figure 6

DRAFT - NOT FOR DISTRIBUTION

Orthopedics

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

www.smith-nephew.com

Telephone: 901-396-2121
Information: 1-800-821-5700
Orders/inquiries: 1-800-238-7538

Design Verification Tests – Smith & Nephew Modular Femoral (Hemi) Heads

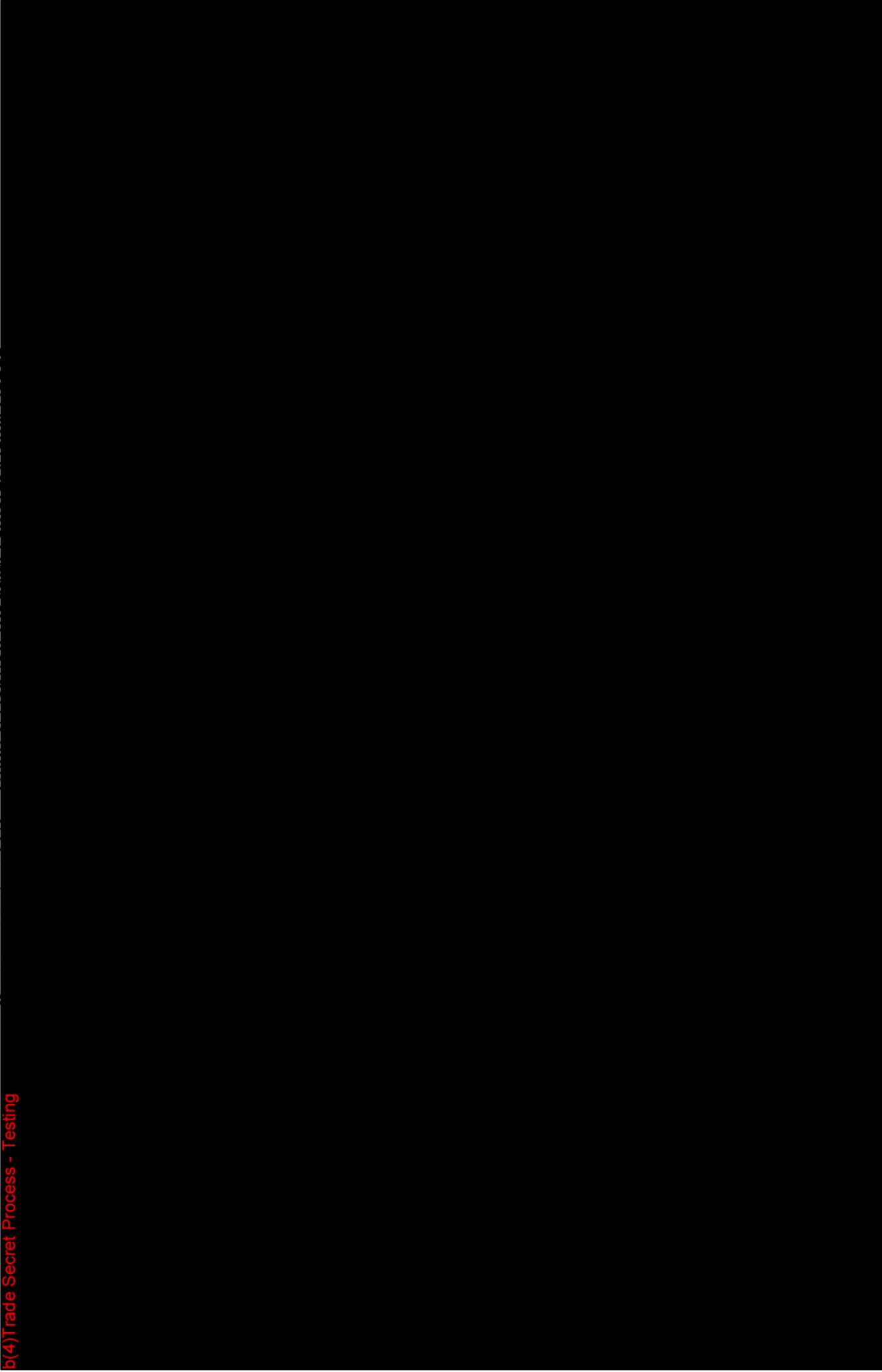
Evaluation conducted per the requirements of the Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Testing Acetabular Cup Prosthesis dated May 1995

Design Aspect Reviewed	Change	Risk	Verification Activity/ Acceptance Criteria	Results of Verification/Design Aspect Information
Materials	No Change	N/A	N/A	<p>The subject Smith & Nephew Modular Femoral (Hemi) Heads will be manufactured from cast Cobalt-Chromium-Molybdenum alloy (CoCrMo) conforming to ASTM F 75.</p> <p>The taper sleeves will be manufactured from wrought Cobalt-Chromium-Molybdenum alloy (CoCrMo) conforming to ASTM F 1537.</p>
Other Components and Tissues Contacting the Devices	No Change	N/A	N/A	<p>The subject Smith & Nephew Modular Femoral (Hemi) Heads will articulate against the natural acetabulum. The components will have the same indications as cleared for market in premarket notification K061243.</p>
Range of Motion	No Change	N/A	N/A	<p>The subject Smith & Nephew Modular Femoral (Hemi) Heads will articulate against the natural acetabulum. The subject devices will be offered in the same range of sizes (38-58mm) and will feature the same articular surface geometry as the predicate devices cleared for market in premarket notification 510(k) K061243. It should also be noted that ROM can be affected by a change in neck diameter. Since the physical boundaries of the sleeves do not add any additional size to the femoral neck diameter in areas where the neck would make contact during joint movement, the ROM of the modular (hemi) heads will not be affected. It is expected that the range of motion will be equivalent to what was found for the modular femoral heads subject of 510(k) K061243.</p>
Cyclic Wear	No Change	N/A	N/A	<p>The overall design and material (Co-Cr-Mo) of the subject Smith & Nephew Modular Femoral (Hemi) Heads is the same as the existing Smith & Nephew modular femoral heads cleared under premarket notification 510(k) K061243. It should also be noted that the articulating surface of the modular femoral heads will be polished to a smooth surface finish of (b)(4) Trade Secret Process which is the same Ra finish identified for the existing Smith & Nephew modular femoral heads cleared under premarket notification 510(k) K061243.</p>

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Design Verification Tests – Smith & Nephew Modular Femoral (Hemi) Heads

b(4) Trade Secret Process - Testing

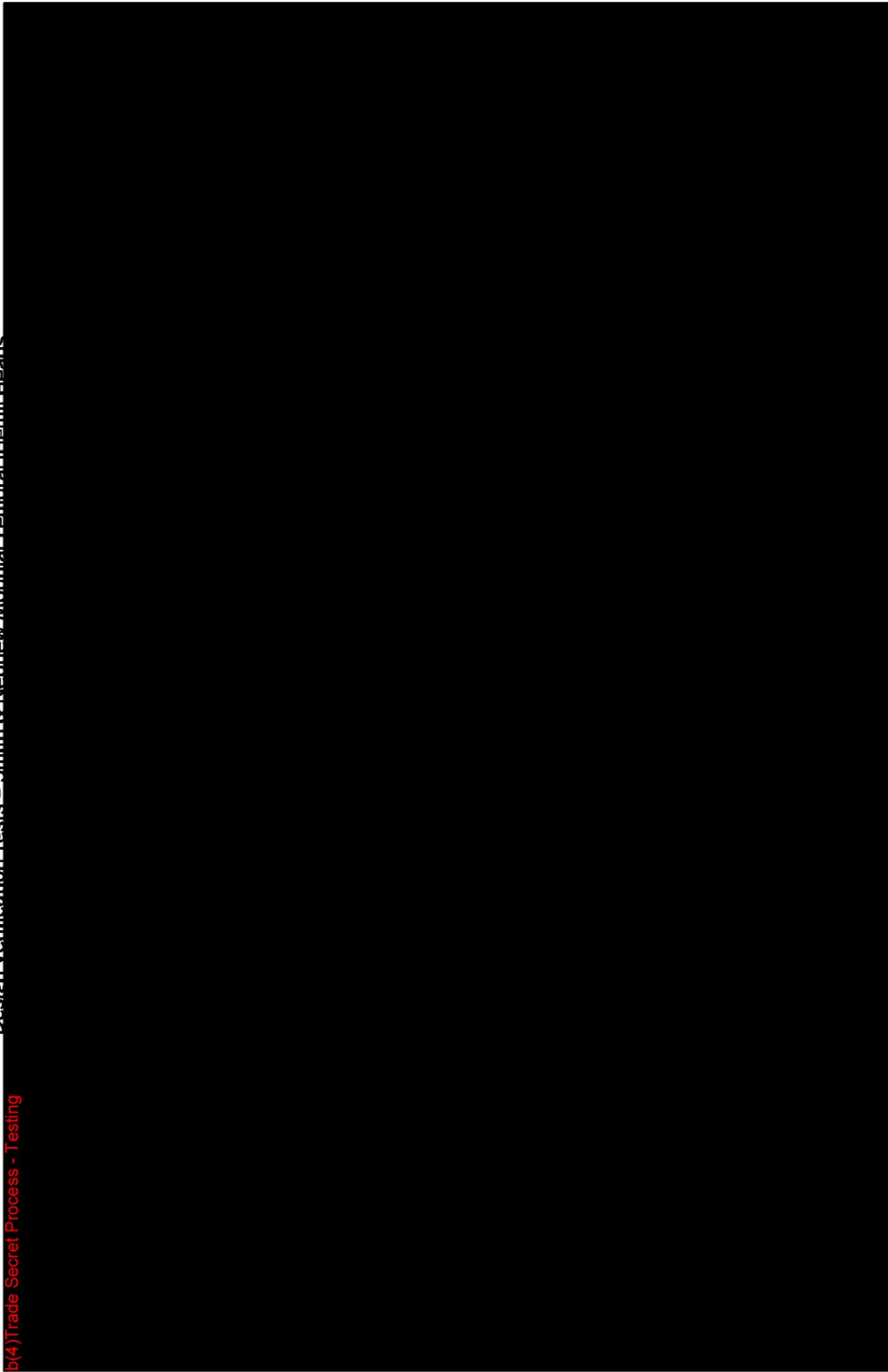


CONFIDENTIAL

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Design Verification Tests – Smith & Nephew Modular Femoral/Hemil Heads

b(4)Trade Secret Process - Testing



CONFIDENTIAL

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Design Verification Tests – Smith & Nephew Modular Femoral (Hemi) Heads

b(4) Trade Secret Process - Testing

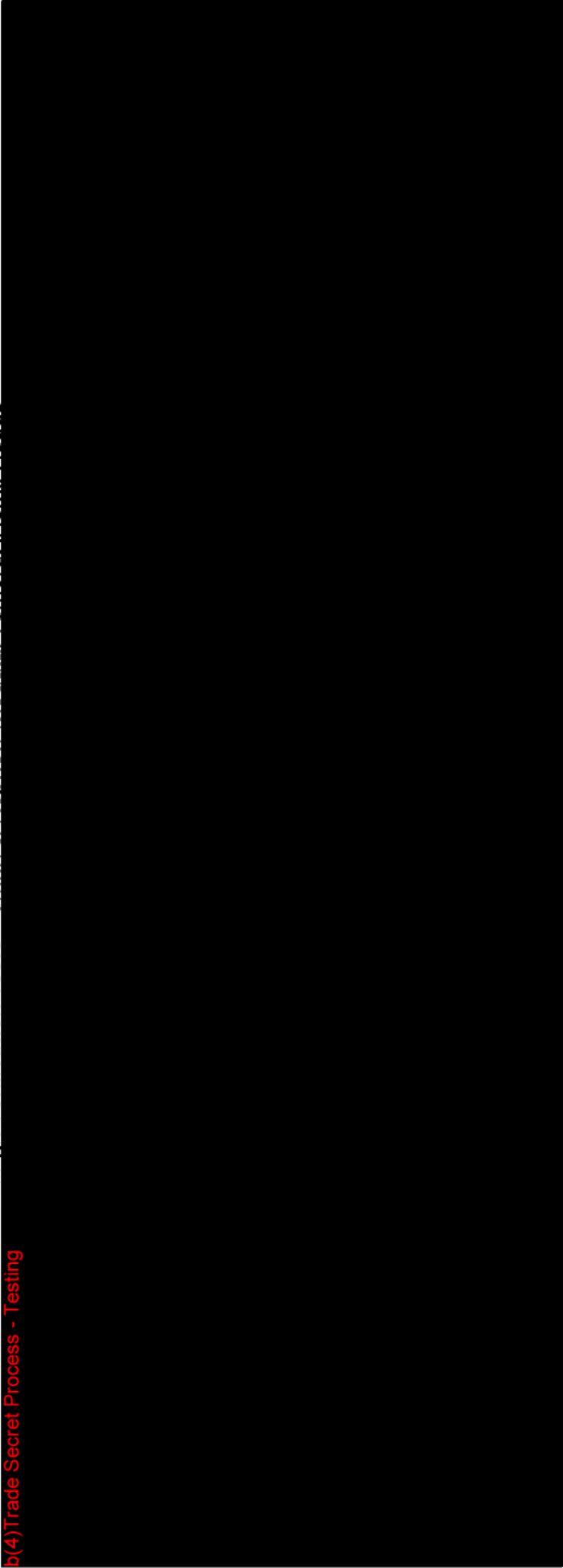


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CONFIDENTIAL

Design Verification Tests – Smith & Nephew Modular Femoral (Hemil) Heads

(b)(4) Trade Secret Process - Testing



⁷ Orthopaedic Research Report OR-04-83, "Torque Testing of Midland Medical Technologies 38mm and 58mm Femoral Heads," June 2004.

CONFIDENTIAL

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JUL 17 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

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Page 2 - Mr. Gino J. Rouss, MS

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,



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

Enclosure

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

Page 1 of 1

510(k) Number K061243

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RECEIVED
FEB 21 1990

FEB 15 1990

Food and Drug Administration
1300 Piccard Drive
Rockville, MD 20850

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

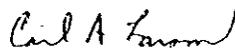
Dear Mr. Games:

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 (Pre-market 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 pre-market 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, Ph.D.
Director, Division of Surgical and
Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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From: Reviewer(s) - Name(s) 70 Suu

Subject: 510(k) Number K062408

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? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Is this device subject to the Tracking Regulation? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Was clinical data necessary to support the review of this 510(k)? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Is this a prescription device? | <input checked="" type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Was this 510(k) reviewed by a Third Party? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Special 510(k)? | <input checked="" type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> 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 days

Predicate Product Code with class: _____ Additional Product Code(s) with panel (optional): _____

Review: KWL/2 05DB 9/8/06
(Branch Chief) (Branch Code) (Date)

Final Review: Carlene Friedman 9/8/06
(Division Director) (Date)

SPECIAL 510(k): Device Modification Review Memorandum

To: K062408

From: Pei Sung, Ph.D.

Recommendation: "SE"

7/2 9/6/06

ZLF
9/8/06

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable:

BDB 7/5/06

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the INDICATION/INTENDED USE of the modified device as described in its labeling HAS NOT CHANGED along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
3. A description of the device MODIFICATIONS, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the FUNDAMENTAL SCIENTIFIC TECHNOLOGY of the modified device has not changed.
4. Comparison Information similarities to applicant's legally marketed predicate device (i.e., K061243) including, labeling, intended use, and physical characteristics.
5. A Design Control Activities Summary (See **Exhibit 11**).
6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm. "SE" is recommended.

Indications: (Same as K061243)

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.

Modification:

The modified femoral heads feature a female Morse-type taper (5° 40' angle) to accept a taper sleeve (2.9 mm/thick, 15.3 mm/long, 5° 40' angles, inner and outer) and to create a neck length offsets of +8mm for the device system.

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The modular femoral heads are offered in sizes ranging from 38-58mm and are made of CoCr alloy.

A summarized device comparison table is listed below:

	Subject Device Modular Femoral Heads (Hemi)	Predicate (K061243) Modular Femoral Heads (Hemi)
Device Design	<ul style="list-style-type: none"> - Modular Taper Connection - Size Range: 38-58 mm - Taper Sleeves allow use with 12/14 Stems - -4, +0, +4, or +8mm neck lengths - Material: CoCr 	<ul style="list-style-type: none"> - Modular with 12/14 Taper - Size Range: 38-58 mm - -8, -4, +0, or +4mm neck lengths - Material: CoCr

The same taper sleeve was cleared via K896580 for S&N's Unipolar Femoral Head system.

Contact Person:

Mr. Gino J. Rouss
 Project Manager – Regulatory Affairs
 Smith & Nephew Orthopaedics
 1450 E. Brooks Road
 Memphis, TN 38116
 Tel: (901) 399-6707
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Re: K062408

Trade/Device Name:
 Regulation Number: 21 CFR 888.3040
 Regulation Name: Smooth or threaded metallic bone fixation fastener
 Regulatory Class: Class II
 Product Code:
 Dated: , 2006
 Received: , 2006

Decision Making Documentation

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

	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 #91-2 and Federal Register 90N0332, September 10, 1991.		

Screening Checklist

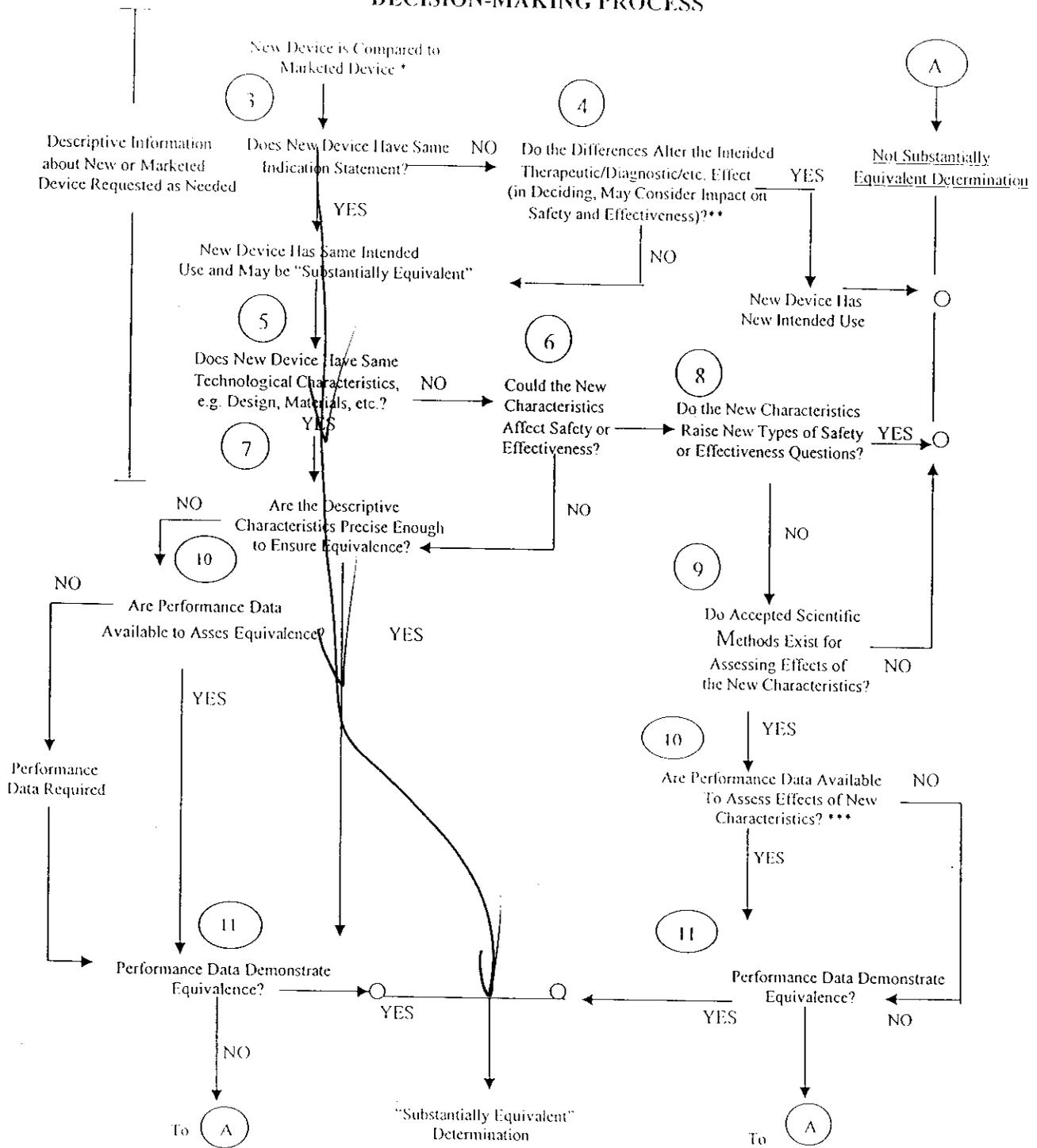
2. GENERAL INFORMATION: REQUIRED IN SPECIAL 510(K) SUBMISSIONS						
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	NA		YES		NO	
	SPECIALS		ABBREVIATED		TRADITIONAL	
	YES	NO	YES	NO	YES	NO
a) trade name, classification name, establishment registration number, 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					
d) compliance with Section 514 - performance standards	NA					
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 named legally marketed equivalent device	x					
m) If kit, kit certification						
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE						
a) Name & 510(k) number of legally marketed (unmodified) predicate device	x					
b) STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*	x		* If no - STOP not a special			
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*	x		* If no - STOP not a special			
d) Design Control Activities Summary	x					
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis	x					
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied	x					
iii) A declaration of conformity with design controls.	x					

Passed Screening: Yes

Reviewed by: Pei Sung

Concurred by: SLF 9/8/06

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.