Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017. K042515

Smith & Nephew, Inc.
Summary of Safety and Effectiveness
High Performance Knee

MAR 1 4 2005

Contact Person and Address

Janet Johnson Akil
Director, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116
(901) 399-5153

Date of Summary: September 15, 2004

Name of Device: High Performance Knee
Common Name: Knee prosthesis

Device Description
The High Performance Knee consists of femoral, tibial insert and patellar components to be used with existing Genesis II tibial trays. The High Performance Knee is a total knee system which provides the ability for greater flexion to those patients who have the anatomical capability to allow a greater flexion range.

Device Classification
21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis – Class II

Mechanical and Clinical Data
A review of the mechanical test data indicated that the High Performance Knee is equivalent to devices currently used clinically and is capable of withstanding expected *in vivo* loading without failure.

Indications for Use
Total knee components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result; failed osteotomies, unicompartmental replacement, or total knee replacement. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are absent or incompetent and the collateral ligaments remain intact. Smith & Nephew, Inc. High Performance Knee components are indicated for use only with cement and are single use devices.

Substantial Equivalence Information
The substantial equivalence of the High Performance Knee is based on its similarities in indications for use, design features, operational principles, and material composition to the following predicate devices – Smith & Nephew Genesis II Knee System and Genesis II & Profix Zirconium Femoral Knee Components (K951987 and K962557, respectively) and the Zimmer NexGen Complete Knee Solution LPS-Flex Fixed Bearing Femoral and Articular Surface Components (K991581).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 09-13-2017

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2005

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

Re: K042515
Trade/Device Name: High Performance Knee
Regulation Numbers: 21 CFR 888.3560
Regulation Names: Knee joint, patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: JWH
Dated: March 1, 2005
Received: March 2, 2005

Dear Ms. Akil:

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N Melkerson

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

Indications for Use

510(k) Number (if known): K042515

Device Name: High Performance Knee

Indications for Use:

Total knee components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result; failed osteotomies, unicompartmental replacement, or total knee replacement. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are absent or incompetent and the collateral ligaments remain intact. Smith & Nephew, Inc. High Performance Knee components are indicated for use only with cement and are single use devices.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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

Page 1 of _____

510(k) Number K042515

Questions? Contact FDA/CDRH/OSE/Image Processing at FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2005

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

Re: K042515
Trade/Device Name: High Performance Knee
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

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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.

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Sincerely yours,

for Mark N Melkerson

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

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510(k) Number (if known): K042515

Device Name: High Performance Knee

Indications for Use:

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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)

for Mark N Melkerson

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

Page 1 of _____

510(k) Number K042515

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

December 28, 2004

SMITH & NEPHEW, INC.
ORTHOPAEDIC DIVISION
1450 E. BROOKS RD.
MEMPHIS, TN 38116
ATTN: JANET JOHNSON AKIL

510(k) Number: K042515
Product: SMITH & NEPHEW, INC. HIGH PERFORMANCE KNEE

Extended Until: 07-MAR-2005

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

Orthopaedics
Smith & Nephew Inc
1450 Brooks Rd
Memphis TN 38116 USA

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

We are smith&nephew

December 27, 2004

Mr. Peter Allen
Food & Drug Administration
Center for Devices & Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

RE: K042515 – Abbreviated 510(k) for the Smith & Nephew High Performance Knee

Dear Mr. Allen:

Please allow this letter to serve as Smith & Nephew Inc.'s request to keep the High Performance Knee Abbreviated Premarket Notification filing open for an additional 45 days. Smith & Nephew is working to gather the additional information that you have requested. Should you have any questions or concerns related to the progress of our review on the subject components, please do not hesitate to contact me directly at (901) 399-5520 or via email at jason.sells@smithnephew.com.

Thank You.

Sincerely,

Jason Sells
Regulatory Affairs Specialist

SK15

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 - 2004

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

Re: K042515
Trade Name: Smith & Nephew High Performance Knee
Dated: September 15, 2004
Received: September 16, 2004

Dear Ms. Akil:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information.

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/cdrh/modact/leastburdensome.html

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff 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. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

If you have any questions concerning the contents of the letter, please contact Mr. Peter Allen at (301) 594-2036, extension 157. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Director, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 E. Brooks Road
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Received: September 16, 2004

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You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

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Rockville, Maryland 20850

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

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Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
410	P. Allen	12/1/04						
410	[illegible]	12/1/04						

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

U.S. GOVERNMENT PRINTING OFFICE 1991:519-771

87

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 Division
D.O
f/t: PAllen: 12-xx-04.:tmj:12-01-04

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

September 16, 2004

SMITH & NEPHEW, INC.
ORTHOPAEDIC DIVISION
1450 E. BROOKS RD.
MEMPHIS, TN 38116
ATTN: JANET JOHNSON AKIL

510(k) Number: K042515
Received: 16-SEP-2004
Product: SMITH & NEPHEW, INC. HIGH PERFORMANCE KNEE

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

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

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

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

Sincerely yours,

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

Form Approved:OMB No. 0910-0511 Expiration Date: August 31, 2006. See instructions for OMB Statement.

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

PAYMENT IDENTIFICATION NUMBER: (b)(4) Confidential and Proprietary Information
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 submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a 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 transfers.
6. Include a copy of the completed 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 & NEPHEW, INC.
1450 BROOKS ROAD
MEMPHIS, TN 38116

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4) Confidential and

2. CONTACT NAME
JASON SELLS

2.1 E-MAIL ADDRESS
jason.sells@smithnephew.com

2.2 TELEPHONE NUMBER (Include Area Code)
901-399-5520

2.3 FACSIMILE (FAX) NUMBER (Include Area Code)
901-398-5146

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/oc/mdufma

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

3.1 Select one of the types below:
- [x] Original Application

Supplement Types:
- [ ] Efficacy (BLA)
- [ ] Panel Track (PMA, PMR, PDP)
- [ ] Real-Time (PMA, PMR, PDP)
- [ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)

- [ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
- [x] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE **EXCEPTIONS**? IF SO, CHECK THE APPLICABLE EXCEPTION.

- [ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
- [ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- [ ] The sole purpose of the application is to support conditions of use for a pediatric population
- [ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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

- [ ] YES
- [x] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2004)
(b)(4) Confidential and Proprietary

Form FDA 3601 (08/2003)

OK

SK 17

109

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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K042515

We are **smith&nephew**

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

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

September 15, 2004

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: Abbreviated 510(k) for the Smith & Nephew High Performance Knee

Dear Sir or Madam:

The purpose of this letter is to notify FDA of our intent to market the Smith & Nephew High Performance Knee. Smith & Nephew is submitting an Abbreviated 510(k) in accordance with requirements set forth in *The New 510(k) Paradigm: Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications*, dated March 20, 1998. The Smith & Nephew High Performance Knee components conform to the *Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-Constrained Total Knee Prostheses* dated April 1993.

We consider our intent to market these devices to be confidential, commercial information, and therefore, it is exempt from public disclosure. To the best of my knowledge, neither I nor anyone else has disclosed through advertising or any other manner our intent to market these devices, except to employees of, or paid consultants to, our company or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy.

We believe this information fulfills the requirements for the present Abbreviated 510(k) submission. Should additional clarification or information be required, please do not hesitate to contact me directly at 901-399-5520 or by FAX at 901-398-5146.

Sincerely,

Janet Johnson Akil

Janet Johnson Akil
Director, Regulatory Affairs

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

High Performance Knee
Table of Contents

SECTION	PAGE NUMBER
I. ADMINISTRATIVE INFORMATION	1
A. TRUTHFUL AND ACCURATE CERTIFICATION	Exhibit 1
B. 510(K) SUMMARY AND INDICATIONS STATEMENT	Exhibit 2
C. MANUFACTURER IDENTIFICATION Manufacturer's Name Establishment Registration Number Primary and Secondary Contact	1
D. DEVICE IDENTIFICATION Proprietary Name Common Name, Classification Name and Reference Device Classification for the Predicate Device Device Product Code and Panel Code	1
II. DEVICE INFORMATION	2
A. INTENDED USE	2
B. DEVICE DESCRIPTION	2
C. MATERIAL INFORMATION	4
D. STERILIZATION INFORMATION	5
E. LABELING	6
F. TESTING INFORMATION	6
G. SUBSTANTIAL EQUIVALENCE INFORMATION	7

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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ABBREVIATED PREMARKET NOTIFICATION
High Performance Knee

I. ADMINISTRATIVE INFORMATION

A. The **TRUTHFUL AND ACCURATE STATEMENT** is provided as **Exhibit 1**.

B. The **510(k) SUMMARY** and **INDICATIONS STATEMENT** are provided as **Exhibit 2**.

C. MANUFACTURER IDENTIFICATION

Manufacturer's Name:	Smith & Nephew, Inc. Orthopaedic Division 1450 E. Brooks Road Memphis, Tennessee 38116
Establishment Registration Number:	1020279
Primary Contact:	Janet Johnson Akil Director, Regulatory Affairs (901) 399-5153 janet.akil@smithnephew.com
Secondary Contact:	Jason Sells Regulatory Affairs Specialist (901) 399-5520 jason.sells@smithnephew.com

D. DEVICE IDENTIFICATION

Proprietary Name

Smith & Nephew, Inc. High Performance Knee

Common Name

Knee Prosthesis

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

Classification Name and Reference

21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis – Class II

Device Classification for the Predicate Device

21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis – Class II

Device Product Code and Panel Code

Orthopaedics/87 JWH

II. DEVICE INFORMATION

A. INTENDED USE

Total knee components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result; failed osteotomies, unicompartmental replacement, or total knee replacement. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are absent or incompetent and the collateral ligaments remain intact. Smith & Nephew, Inc. High Performance Knee components are indicated for use only with cement and are single use devices.

The indications listed above are substantially equivalent to indications for use cleared in premarket notifications listed below.

DESCRIPTION	SUBMISSION NUMBER	CLEARANCE DATE
Genesis P/S Knee System	K946088	8/8/95
Genesis II Knee System	K951987	8/22/95
Profix P/S Knee System	K954909	1/31/96
Genesis II P/S High Flexion Articular Insert	K032295	8/21/03

B. DEVICE DESCRIPTION

Subject of this premarket notification is the Smith & Nephew High Performance Knee. The High Performance Knee is a posterior stabilized total knee system which provides the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

113

Page 003 processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

ability for greater flexion to those patients who have the anatomical capability to allow a greater flexion range. Components of this premarket notification include:

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[1] Engineering drawings of the Genesis II tibial tray components are included as part of Exhibit 10 of K951987.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]

115

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

G. SUBSTANTIAL EQUIVALENCE INFORMATION

The overall design of the Smith & Nephew High Performance Knee is substantially equivalent to previously cleared devices listed below.

MANUFACTURER	DESCRIPTION	510(K)	CLEARANCE DATE
Smith & Nephew, Inc.	Genesis P/S Knee System	K946088	8/8/95
Smith & Nephew, Inc.	Genesis II Knee System	K951987	8/22/95
Smith & Nephew, Inc.	Profix P/S Knee System	K954909	1/31/96
Osteonics Corp.	Scorpio Posteriorly Stabilized Total Knee System	K962152	8/14/96
Wright Medical Technology	Advance Knee System	K972626	9/29/97
Zimmer, Inc.	NexGen Complete Knee Solution LPS-Flex Fixed Bearing Femoral and Articular Surface Components	K991581	7/30/99

The indications for use for the Smith & Nephew High Performance Knee are substantially equivalent to indications for use cleared in premarket notifications listed below.

MANUFACTURER	DESCRIPTION	510(K)	CLEARANCE DATE
Smith & Nephew, Inc.	Genesis P/S Knee System	K946088	8/8/95
Smith & Nephew, Inc.	Genesis II Knee System	K951987	8/22/95
Smith & Nephew, Inc.	Profix P/S Knee System	K954909	1/31/96
Smith & Nephew, Inc.	Genesis II P/S High Flexion Articular Insert	K032295	8/21/03

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Page 119 of 119 processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]

In summary, the Smith & Nephew, Inc. High Performance Knee is similar in design, function, intended use, and material composition to predicate devices. While the subject device is not identical to all of the predicates, any differences that may exist between the subject device and the predicates identified above do not significantly affect the safety or effectiveness of the device. Therefore, it is concluded that the Smith & Nephew High Performance Knee is substantially equivalent to currently marketed predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

High Performance Knee
List of Exhibits

Exhibit 1	Truthful and Accurate Statement
Exhibit 2	510(k) Summary of Safety and Effectiveness and Indications Statement
Exhibit 3	Schematics of High Performance Knee Femoral Component
Exhibit 4	Schematics of High Performance Knee Articular Insert
Exhibit 5	Engineering Drawings
Exhibit 6	Component Descriptions
Exhibit 7	Summary Document per *Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-Constrained Total Knee Prostheses* dated April 1993
Exhibit 8	Sterilization Information
Exhibit 9	Sample Representative Carton Labels
Exhibit 10	Package Insert
Exhibit 11	Draft Surgical Technique

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

Premarket Notification
Truthful & Accurate Statement

I certify that, in my capacity as Director of Regulatory Affairs, for the Orthopaedics Division of Smith & Nephew, Inc., 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.

Janet Johnson Akil

Janet Johnson Akil
Director, Regulatory Affairs

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

Indications for Use

510(k) Number (if known): K042515

Device Name: High Performance Knee

Indications for Use:

Total knee components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result; failed osteotomies, unicompartmental replacement, or total knee replacement. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are absent or incompetent and the collateral ligaments remain intact. Smith & Nephew, Inc. High Performance Knee components are indicated for use only with cement and are single use devices.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

Smith & Nephew, Inc.
Summary of Safety and Effectiveness
High Performance Knee

Date of Summary: September 15, 2004

Contact Person and Address

Janet Johnson Akil
Director, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116
(901) 399-5153

Name of Device: High Performance Knee
Common Name: Knee prosthesis

Device Description

The High Performance Knee consists of femoral, tibial insert and patellar components to be used with existing Genesis II tibial trays. The High Performance Knee is a total knee system which provides the ability for greater flexion to those patients who have the anatomical capability to allow a greater flexion range.

Device Classification

21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis – Class II

Mechanical and Clinical Data

A review of the mechanical test data indicated that the High Performance Knee is equivalent to devices currently used clinically and is capable of withstanding expected *in vivo* loading without failure.

Indications for Use

Total knee components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result; failed osteotomies, unicompartmental replacement, or total knee replacement. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are absent or incompetent and the collateral ligaments remain intact. Smith & Nephew, Inc. High Performance Knee components are indicated for use only with cement and are single use devices.

Substantial Equivalence Information

The substantial equivalence of the High Performance Knee is based on its similarities in indications for use, design features, operational principles, and material composition to the following predicate devices – Smith & Nephew Genesis II Knee System and Genesis II & Profix Zirconium Femoral Knee Components (K951987 and K962557, respectively) and the Zimmer NexGen Complete Knee Solution LPS-Flex Fixed Bearing Femoral and Articular Surface Components (K991581).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]

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Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

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

T 901-
F 901-
www.smith-nephew.com

We are smith&nephew

To	FDA
From	Jason Sells
Date	September 15, 2004
Subject	High Performance Knee Drawing Prints

Representative drawing prints of the High Performance Knee femoral, articular insert, and patellar components are provided in Exhibit 5.

(b)(4) Confidential and Proprietary Information

[redacted]

Memo

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information

[redacted]

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Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

SUMMARY REPORT

Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-Constrained Total Knee Prostheses

(dated April 1993)

Smith & Nephew High Performance Knee

This Summary Report describes how the applicable guidance document was used during device development and testing to address the risks associated with the subject devices.

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]

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(b)(4) Confidential and Proprietary Information

[redacted]

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(b)(4) Confidential and Proprietary Information

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information

[redacted]

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(b)(4) Confidential and Proprietary Information

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

Orthopaedic Division
Smith & Nephew, Inc.
1450 Brooks Rd., Memphis, TN 38116 U.S.A.
901-396-2121, For information: 1-800-821-5700
For orders and order inquiries: 1-800-238-7538

Smith+Nephew

Specification: *Q109124a*

Form Date: 03/2002

Title: *LABEL SPECIFICATION*

LABEL TEXT REVISION:	SAMPLE

OUTER LABEL

REF DL7321
HIGH PERFORMANCE KNEE

QTY: (1)

5
SIZE
TAILLE
GROSSE
TALLA
MISURA

OXINIUM®

FEMORAL COMPONENT
PROTHESE FEMORALE
FEMUR KOMPONENTE
COMPONENTE FEMORAL
COMPONENTE FEMORALE

RIGHT
DROIT
RECHTS
DERECHA
DESTRO

LOT NO. SAMPLE

HIGH PERFORMANCE KNEE
A/P 62 MM, M/L 70 MM
FOR CEMENTED USE ONLY
ZR-2.5NB

LOT SAMPLE

STERILE R

2014/09

H435DL73211W
$SAMPLEWH

INNER LABEL

REF DL7321
SIZE 5, RIGHT

smith&nephew

QTY: (1)

HIGH PERFORMANCE KNEE
OXINIUM®
FEMORAL COMPONENT

H435DL73211W
$SAMPLEWH

LOT SAMPLE

STERILE R

2014/09

CHART-STIK® LABEL

CHART-STIK® LABEL
REF DL7321
SIZE 5, RIGHT

ATTACH TO PATIENT'S RECORD

HIGH PERFORMANCE KNEE
OXINIUM®
FEMORAL COMPONENT

H435DL73211W
$SAMPLEWH

smith&nephew LOT SAMPLE

155

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Orthopaedic Division

Smith & Nephew, Inc.
1450 Brooks Rd., Memphis, TN 38116 U.S.A.
901-396-7121, For information: 1-800-821-8700
For orders and order inquiries: 1-800-238-7358

Smith+Nephew

Specification: Q109124a

Form Date: 03/2002

Title: LABEL SPECIFICATION

LABEL TEXT REVISION: **SAMPLE**

OUTER LABEL

REF DL7321
HIGH PERFORMANCE KNEE
MEDIUM PRIMARY P/S
ARTICULAR INSERT
INSERT ARTICULAIRE
TIBIA-EINSATZ
INSERTO ARTICULAR
INSERTO ARTICOLARE

LOT NO. SAMPLE

QTY: (1)
5-6
SIZE
TAILLE / GRÖSSE
TALLA / MISURA
13 MM
RIGHT
DROIT / RECHTS
DERECHA / DESTRO

HIGH PERFORMANCE KNEE
ARTICULAR INSERT
A/P 52 MM, M/L 74 MM
FOR CEMENTED USE ONLY
UHMWPE

LOT SAMPLE

STERILE EO

2014/09

+H435DL73211W
+$SAMPLEWH

INNER LABEL

REF DL7321
SIZE 5-6, RIGHT
13 MM
HIGH PERFORMANCE KNEE
MEDIUM PRIMARY P/S
ARTICULAR INSERT

smith&nephew

QTY: (1)

+H435DL73211W
+$SAMPLEWH

LOT SAMPLE

STERILE EO

2014/09

CHART-STIK® LABEL

CHART-STIK® LABEL
REF DL7321
SIZE 5-6, RIGHT
13 MM
HIGH PERFORMANCE KNEE
MEDIUM PRIMARY P/S
ARTICULAR INSERT

ATTACH TO PATIENT RECORD

+H435DL73211W
+$SAMPLEWH

smith&nephew LOT SAMPLE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Orthopaedic Division

Smith & Nephew, Inc.
1450 Brooks Rd., Memphis, TN 38116 U.S.A.
901-396-2121. For information: 1-800-821-5700
For orders and order inquiries: 1-800-238-7538

Smith+Nephew

Specification: *Q109124a*

Form Date: 03/2002

Title: *LABEL SPECIFICATION*

LABEL TEXT REVISION:	SAMPLE

OUTER LABEL

REF DL7321
HIGH PERFORMANCE
PATELLAR COMPONENT
PROTHESE ROTULIENNE
PATELLA KOMPONENTE
COMPONENTE RATELAR
COMPONENTE ROTULEO

RESURFACING
29 MM
MEDIUM

QTY: (1)

smith&nephew LOT NO. SAMPLE

PATELLAR COMPONENT
FOR CEMENTED USE ONLY
UHMWPE

+H435DL7321W
+$SAMPLEWH

LOT SAMPLE

STERILE EO

2014/09

Smith & Nephew, Inc. Memphis, TN 38116 USA

EC REP: Smith & Nephew Orthopaedics GmbH, Tuttlingen, Germany

INNER LABEL

REF DL7321
MEDIUM
29 MM
HIGH PERFORMANCE KNEE
RESURFACING
PATELLAR COMPONENT

smith&nephew

QTY: (1)

+H435DL7321W
+$SAMPLEWH

LOT SAMPLE

STERILE EO

2014/09

CHART-STIK® LABEL

CHART-STIK® LABEL
REF DL7321
MEDIUM
29 MM
HIGH PERFORMANCE KNEE
RESURFACING
PATELLAR COMPONENT

ATTACH TO PATIENTS RECORD

+H435DL7321W
+$SAMPLEWH

smith&nephew LOT SAMPLE

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LABEL TEXT REVISION:	SAMPLE

OUTER LABEL

REF DL7321
HIGH PERFORMANCE
PATELLAR COMPONENT
PROTHESE ROTULIENNE
PATELLA KOMPONENTE
COMPONENTE PATELAR
COMPONENTE ROTULEO

BICONVEX
29 MM
MEDIUM

QTY: (1)

smith&nephew

LOT NO. SAMPLE

PATELLAR COMPONENT
FOR CEMENTED USE ONLY
UHMWPE

LOT SAMPLE

STERILE EO

2014/09

Smith & Nephew, Inc. Memphis, TN 38116 USA

EC REP: Smith & Nephew Orthopaedical GmbH, Tuttlingen Germany

INNER LABEL

REF DL7321
MEDIUM
29 MM
HIGH PERFORMANCE KNEE
BICONVEX
PATELLAR COMPONENT

smith&nephew

QTY: (1)

+H435DL73211W

+$SAMPLEWH

LOT SAMPLE

STERILE EO

2014/09

CHART-STIK® LABEL

CHART-STIK® LABEL
REF DL7321
MEDIUM
29 MM
HIGH PERFORMANCE KNEE
BICONVEX
PATELLAR COMPONENT

ATTACH TO PATIENT'S RECORD

+H435DL73211W

+$SAMPLEWH

smith&nephew LOT SAMPLE

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

T 901-
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We are smith&nephew

To FDA

From Jason Sells

Date September 15, 2004

Subject Sample carton label – Oval resurfacing patellas

The High Performance Knee system features oval-shaped resurfacing patellar components. Sample labels for this product are not available at this time, but a general label is provided below. The High Performance Oval Patella labels will have the same general information (e.g. sterilization, package insert, single use, cemented use only) as the Biconvex and Resurfacing patella labels, but will also have information specific to the Oval Patella (e.g. catalog number, size description, picture).

REF 740246XX
HIGH PERFORMANCE
PATELLAR COMPONENT

OVAL
XX mm
MEDIUM

{Picture}

LOT NO. XXXXXXXX

smith&nephew

PATELLAR COMPONENT
FOR CEMENTED USE ONLY
UHMWPE

LOT NO. XXXXXXXX

STERILE

SINGLE USE ONLY
Expiration Date: YYYY/MM
Package Insert Enclosed

Memo

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Knee Systems

Important Medical Information

Description of System

Smith & Nephew Knee Systems consist of femoral components, tibial components, and accessories. The component material is provided on the outside carton label. Femoral and tibial components are available in porous and non-porous options. Non-porous components, PROFIX® porous coated no-hole tibial bases and porous plus hydroxylapatite (HA) coated no-hole tibial bases are to be used with cement. Semi-constrained porous coated devices, porous plus HA coated devices and HA coated devices of the PROFIX Total Knee System and GENESIS® II Total Knee System may be used without cement. Constrained tibial inserts may only be used with cemented femoral and cemented tibial components. Hydroxylapatite (HA) coatings include HA that is supplied either on a grit blasted or porous surface.

Each total knee system is designed as a system and does not allow the substitution of components from other systems or manufacturers. All implantable devices are designed for single use only.

Some of the alloys needed to produce orthopedic implants contain some metallic components that may be carcinogenic in tissue cultures or intact organism under very unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified convincing evidence of such phenomenon, in spite of the millions of implants in use.

Indications, Contraindications, and Adverse Effects

The general principles of good patient selection and sound surgical judgment apply to the total knee procedure. Preoperative planning and meticulous surgical technique are essential to achieve optimum results. Considerations of anatomic loading, soft-tissue condition, and component placement are critical to minimize a variety of postoperative complications.

Indications for Total Knee Replacement

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.
5. Constrained knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent.

Contraindications for Total Knee Replacement

1. Cases where there is poor bone stock which would make the procedure unjustifiable
2. Active, local infection or previous intra-articular infections

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3. Mental or neurologic conditions that tend to pre-empt the patient's ability or willingness to restrict activities
4. Neuropathic (Charcot) joint
5. Conditions that tend to place increased loads on implants such as age, weight, and activity level, which are incompatible with a satisfactory long-term result
6. Collateral ligament insufficiency (except in cases where a constrained knee system is indicated and used)
7. Skeletal immaturity
8. Use of a supracondylar nail through intercondylar notch of PROFIX primary femoral components
9. Use of slotted femoral and tibial stems without adequate bone support.

Indications for Unicompartmental Knee Replacement

1. Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2. Correction of functional deformity
3. Revision procedures where other treatments or devices have failed; and
4. Treatment of fractures that are unmanageable using other techniques.

Contraindications for Unicompartmental Knee Replacement

The contraindications for Unicompartmental Knee Replacement include all of the contraindications listed for Total Knee Replacement.

Possible Adverse Effects

1. Wear of the polyethylene articulating surfaces of knee replacement components has been reported following total knee replacement. Higher rates of wear may be initiated by particles of cement, metal, or other debris which can cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis, and lead to early revision surgery to replace the worn prosthetic components.
2. With all joint replacements, asymptomatic, localized, progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to particulate wear debris. Particles are generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Secondarily, particles may also be generated by third-body wear. Osteolysis can lead to future complications necessitating the removal and replacement of prosthetic components.
3. Loosening, bending, cracking, or fracture of implant components. Fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.
4. Dislocation, subluxation, excessive rotation, flexion contracture, decreased range of motion, lengthening or shortening of the leg, looseness of components, unusual stress concentrations, and extraneous bone can result from trauma, improper implant selection, improper implant positioning, improper fixation, and/or migration of the components. Muscle and fibrous tissue laxity can also contribute to these conditions.
5. Tibia, femur, or patella fractures.
6. Acute post-surgical wound infection, late deep wound sepsis and/or low-grade synovitis.

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7. Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage has been reported, and may be a result of surgical trauma. Temporary or permanent nerve damage can result in pain or numbness of the affected limb.
8. Wound hematoma, thromboembolic diseases including venous thrombosis, pulmonary embolus, or myocardial infarction.
9. Myositis ossificans. Periarticular calcification or ossification, with or without impediment to joint mobility. Periarticular calcification can cause decreased range of motion.
10. Skin sloughs or delayed wound healing.
11. Although rare, metal sensitivity or allergic reactions in patients following joint replacement have been reported. Implantation of foreign material in tissues can result in histological reactions involving macrophages and fibroblasts.
12. Damage to blood vessels.
13. Varus-valgus deformity.
14. Failure of the porous coating/substrate interface or hydroxylapatite coating/porous coating bonding may result in bead/HA separation.

Warnings and Precautions

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the device does not replace normal healthy bone, and that the implant can break or become damaged as a result of strenuous activity or trauma, and has a finite expected service life and may need to be replaced in the future.

Preoperative

1. Use care in handling and storing of implant components. Cutting, bending, or scratching the surfaces of components can significantly reduce the strength, fatigue resistance and/or wear characteristics of the implant system. These in turn may induce internal stresses that are not obvious to the eye and may lead to fracture of the component. Do not allow the porous surfaces to come in contact with cloth or other fiber releasing materials.
2. Surgical information is available upon request. The surgeon should be familiar with the technique.
3. An adequate inventory of implant sizes should be available at the time of surgery.
4. Intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear and damage prior to surgery.
5. If a computer assisted surgery system is used, consult the applicable software and hardware reference manuals provided by the manufacturer to ensure proper operation of this equipment.

Intraoperative

1. 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, weight, bone and muscle conditions, etc. Generally, the largest cross-section component which will allow adequate bone support to be maintained is preferred. Failure to use the optimum size component may result in loosening, bending, cracking, or fracture of the component and/or bone.
2. Modular components must be assembled securely to prevent disassociation. Avoid repeated assembly and disassembly of the modular components which could compromise a critical locking action of the

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components. Surgical debris must be cleaned from components before assembly. Debris inhibits the proper fit and locking of modular components which may lead to early failure of the procedure.

3. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentration which may lead to failure of the procedure. During curing of cement, care should be taken to prevent movement of the implant components.
4. Fixation screws, when used, should be fully seated to assure stable fixation, and to avoid interference with the proper seating of components. Use only screws recommended by the manufacturer for the specific prosthesis to avoid improper fit, and to avoid improper mixing of metals.
5. Prior to closure, the surgical site should be thoroughly cleaned of bone chips, extraneous cement, ectopic bone, etc. Foreign particles at the metal and/or plastic interface may cause excessive wear and/or friction.
6. Posterior stabilized knee systems, constrained knee systems, and systems with a deep articular surface should not be utilized without significant adjunctive fixation (stems, screws, etc.).
7. An implant should never be reused. While it may appear undamaged, imperfection may exist which would reduce the service life of the implant.
8. Use the GENESIS Torque Wrench to secure the distal femoral wedges and the conversion modules to the GENESIS femoral component with femoral lugs. Use the GENESIS II Torque Wrench to secure the distal femoral wedges and the conversion modules to the GENESIS II femoral component with femoral lugs. The femoral lugs should be torqued to 70 in-lbs. Use the Mobile Bearing Rotation Peg Torque Wrench to secure the rotation peg to the Mobile Bearing Baseplate. The rotation peg should be torqued to 75 in-lbs.
9. Distal fixation lugs should be used with porous cruciate-retaining femoral components when implanted without cement. These lugs provide medial/lateral stability of the prosthesis.
10. For computer assisted surgery systems, it is extremely important to correctly select input parameters (e.g. bony landmarks). Operators of this equipment should be familiar with the anatomy relevant to the procedure. Failure to provide proper input could cause problems such as violation of critical anatomical structures and malpositioned implants.

Postoperative

1. Postoperative patient care and directions and warnings to patients by physicians are extremely important. Protected weight bearing with external support is recommended for a period of time to allow healing.
2. Use extreme care in patient handling.
3. Postoperative therapy should be structured to prevent excessive loading of the operative knee and to encourage bone healing.
4. Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.

Packaging and Labeling

Knee implants are sterilized products and should only be accepted 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.

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Sterilization/Resterilization

Most implants are supplied sterile and have been packaged in protective packaging. 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

Nonporous or non-HA coated 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 at 10 inHg (339 millibars) minimum.
- For the United Kingdom, sterilization should be carried out in accordance with HTM 2010. The recommended prevacuum sterilization cycle is: Evacuation to 100mBar for 2-3 minutes, Negative Pressure pulsing (5): 800mBar-100mBar, Positive Pressure pulsing (5): 2.2Bar – 1.1 Bar, Sterilization exposure: 3 minutes at 134°-137°C, Drying vacuum 40mBar for 5-10 minutes. Note: mBar absolute.
- Gravity Cycle: 270°F to 275°F (132°C to 135°C) with a minimum dwell time at temperature of 10 minutes, followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.

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

If porous coated or HA coated implants are inadvertently contaminated, return the unsoiled prosthesis to Smith & Nephew for resterilization. DO NOT RESTERILIZE porous coated or HA coated implants. The coating requires special cleaning procedures.

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 millibars)	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.

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Information

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

Manufacturing facilities and EC representative:

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

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

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

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Rev. 0 5/04 CE 0123

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Smith & Nephew High Performance Knee System

Draft Surgical Technique

Surgical Step	Details	Instruments
1. Incision	▪ Open the knee using the desired MIS approach.	▪ Scalpel ▪ Retractors (L-Bent Holmann)
2. Entry Hole – Femur	▪ Open the femoral canal using the 9.5 mm Drill. The distal end of the drill will open the canal to 12 mm. ▪ If desired, use the Drill to open the tibial canal at this step.	▪ 9.5mm Drill
3. IM Referencing	▪ Using the T-Handle, ream the femoral canal with 8 mm IM rod	▪ T-handle quick connect ▪ 8.0mm IM Rod
4. Preliminary Femoral Sizing	▪ Use the preliminary sizer to determine the proper distal resection if the estimated size is between a 2 or 3 or between an 8 and 9.	▪ Sizing Template(s) (Sm, Std, Lg)
5. Valgus Alignment	▪ Place the desired angle Valgus Collet into the Valgus Alignment Guide.	▪ Valgus Alignment Guide with pin holes ▪ Valgus Collet
6. Distal Femoral Resection	▪ Assemble the Distal Cutting Block to the Valgus Alignment Guide using the slide lock on the side of the Cutting Block. ▪ Slide the assembly over the IM rod ▪ Set the rotational alignment of the assembly and pin, if desired ▪ Pin the Distal Block through the two pin sleeves ▪ Adjust the resection height of the Distal Block, if desired, using the central knob, then pin through the oblique hole. ▪ Make the distal resection and then remove the pins and Block ▪ Note: If the patient presents with a flexion contracture, it is advisable to make the tibial resection to check the extension space before making any further femoral resections.	▪ Distal Cutting Block (Sm, Std, Lg) ▪ Bone Spikes ▪ Flexion/Extension Blocks

Surgical Step	Details	Instruments
7. Femoral Sizing	▪ Place the Sizing Guide onto the distal femur. The Quick Connect handle can be used to control the Guide. ▪ Position the medial posterior paddle of the Guide flush against the medial posterior condyle and rotate the Guide to the AP Axis or the Epicondylar Axis to set the external rotation. ▪ Note: To reference the posterior condylar axis, assemble the modular lateral posterior paddle before placing the Guide on the femur. ▪ Place two pins into the Guide to secure rotation. ▪ Place the tip of the Stylus on the anterior cortex and read the size off of the stylus shaft. ▪ If between sizes, the larger size should be selected if true posterior referencing is desired. ▪ Remove the pins and Sizing Guide	▪ Sizing Guide ▪ Pins ▪ Quick Connect Handle
8. AP Resection	▪ Position the appropriate size AP Block onto the distal femur by inserting the fixation pegs into the drilled holes from the Sizing Guide. ▪ The posterior resection will match the implant thickness when the AP Block is in the most posterior position. ▪ If desired, the AP Block can be moved anteriorly to prevent anterior cortical notching if a smaller size was selected in the Sizing step.	▪ AP Block ▪ Bone Spikes

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167

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Surgical Step	Details	Instruments
9. PS Box Resection	▪ Assemble the Femoral Trial onto the Femoral Trial Impactor. ▪ Place the Femoral Trial onto the femur by positioning the proximal edge of the posterior condyles at the proximal end of the posterior resection and then by rotating the femoral trial from posterior to anterior. Pin to secure position. ▪ Slide the PS Collet into the T-slot of the Femoral Trial from the anterior side until the locking pin engages secures the PS Collet. ▪ Insert the PS Reamer into the sliding Reamer Guide and ream from anterior to posterior. Remove any loose material. ▪ Insert the PS Chisel into the PS Collet and impact until flush with the Collet. The PS Chisel will enter into the Collet at a slight posterior angle. ▪ Remove the PS Collet. ▪ Use the rasp to remove the bone in the exposed patellofemoral groove anterior to the PS box cavity. The rasp should be kept parallel to the distal resection. ▪ Note: This step can be completed after the Tibial Resection is completed.	▪ Femoral Trial ▪ Femoral Trial Impactor ▪ PS Collet ▪ PS Reamer ▪ PS Chisel ▪ Osteotome/Rasp

Surgical Step	Details	Instruments
10. Tibia Resection – IM	▪ Open the femoral canal using the 9.5 mm drill. The distal end of the drill will open the canal to 12 mm. ▪ Using the T-Handle, ream the femoral canal with 8 mm IM rod ▪ Slide the IM Tibial Stylus over the IM Rod and reference the medial and lateral styli to the medial and lateral reference points of the tibial condyles. ▪ Rotate the Tibial Stylus until the Tubercle Stylus is aligned with the center of the tubercle. Secure the IM Tibial Stylus to the IM Rod ▪ Slide the Tibial Cutting Block over the Stylus shaft from the distal end. Use the Knob to control the resection level read from the top of the Block on the Stylus shaft. Pin the block into place at the desired resection level. ▪ Remove the Tibial Stylus. ▪ Make the tibial resection.	▪ 9.5mm Drill ▪ 8.0mm IM Rod ▪ T-Handle ▪ IM Tibial Stylus ▪ Tibial Cutting Block ▪ Tubercle Stylus
11. Tibial Resection – EM	▪ Push in the Distal Column's distal lock button and slide the Ankle Clamp through the Column's square hole. ▪ Push in the Column's proximal lock button and slide the Tibial Platform into the Column's circular hole. ▪ Place the Clamp Spring around the ankle and secure both ends to the Ankle Clamp. ▪ Align the Distal Column with the tibial axis and pin the Tibial Platform. ▪ Assemble the Tibial Stylus to the Tibial Block ▪ Slide the Tibial Cutting Block over the upper rod of the Tibial Platform. Use the Knob to control the resection level read from the top of the Block on the Stylus shaft. Pin the block into place at the desired resection level. ▪ Remove the EM Alignment Assembly. ▪ Make the tibial resection.	▪ Ankle Clamp ▪ Clamp Spring ▪ Distal Column ▪ Tibial Platform ▪ Tibial Cutting Block ▪ Tibial Stylus ▪ Pins

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169

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Surgical Step	Details	Instruments
12. Femoral Reduction	▪ Slide the pins of the PS Box Trial from the anterior side into the Femoral Trial's T-slot so that the PS box faces anteriorly. Slide the PS Box Trial posterior and then rotate the Box Trial and engage the anterior locking pins.	▪ PS Box Trial
13. Tibial Reduction	▪ Position the Tibial Trial onto the resected tibial and align the tubercle reference line with the center of the tibial tubercle. Pin to secure the Trial. ▪ After final placement has been determined, punch through the trial with the Stem/Fin Punch. ▪ Insert the modular Stem Trial into the Tibial Trial. or ▪ Position the Tibial Trial onto the resected tibial and align the tubercle reference line with the center of the tibial tubercle. Pin to secure the Trial. ▪ Punch through the Tibial Trial with the Stem Punch ▪ Insert the modular Stem Trial into the Tibial Trial. ▪ After final placement has been determined, punch through the trial with the Stem Punch.	▪ Tibial Trial ▪ Stem Trial ▪ Stem Punch ▪ Fin Punch ▪ Stem/Fin Punch ▪ Articular Trial ▪ Spacer Trials

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Surgical Step	Details	Instruments
14. Patellar Resection (Inset)	▪ Use the Sizer to determine the best fit diameter patellar component. ▪ Assembly the appropriate sized Patellar Reamer Guide over the Patellar Clamp. ▪ Position the Patellar Clamp and Guide over the patella and clamp into place. Tighten the knob to secure the Clamp on the patella. ▪ Assembly the appropriate sized Patellar Biconvex Reamer to the end of the Patellar Reamer Shaft. ▪ Slide the Patellar Reamer Depth Stop over the shaft of the Patellar Reamer Shaft and keep positioned near the chuck end of the Shaft. ▪ Place the Reamer into the Reamer Guide. Position the Sizer around the Shaft between the Guide and the Depth Stop. Slide the Depth Stop down the Shaft until there are no gaps between the Guide, Sizer and Depth Stop. ▪ Remove the Sizer and ream the patella until the Depth Stop is flush with the Guide. ▪ Remove the Clamp and Guide. ▪ Optional: ▪ Position the Patellar Trial into the reamed recess. ▪ Place the Dome Periphery Reamer end into the center hole of the Patellar Trial and ream until flush with the Patellar Trial.	▪ Sizer ▪ Patellar Clamp ▪ Patellar Reamer Guide ▪ Patellar Biconvex Reamer ▪ Patellar Reamer Shaft ▪ Patellar Reamer Depth Stop ▪ Caliper ▪ Patellar Trial ▪ Dome Periphery Reamer

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Surgical Step	Details	Instruments
15. Patellar Resection (Option 1)	▪ Use the Sizer to determine the best fit diameter patellar component. ▪ Assembly the appropriate sized Patellar Reamer Guide over the Patellar Clamp. ▪ Position the Patellar Clamp and Guide over the patella and clamp into place. Tighten the knob to secure the Clamp on the patella. ▪ Assembly the appropriate sized Patellar Resurfacing Reamer to the end of the Patellar Reamer Shaft. ▪ Slide the Patellar Reamer Depth Stop over the shaft of the Patellar Reamer Shaft and keep positioned near the chuck end of the Shaft. ▪ Place the Reamer into the Reamer Guide. Position the Sizer around the Shaft between the Guide and the Depth Stop. Slide the Depth Stop down the Shaft until there are no gaps between the Guide, Sizer and Depth Stop. ▪ Remove the Sizer and ream the patella until the Depth Stop is flush with the Guide. ▪ Remove the Clamp and Guide. ▪ Assembly the appropriate sized Patellar Drill Guide over the Patellar Clamp. ▪ Position the Drill Guide over the resected surface of the patella and secure the Clamp closed with the threaded nut. ▪ Use the Patellar Peg Drill to prepare the three holes through the Guide then remove the Clamp and Drill Guide.	▪ Sizer ▪ Patellar Clamp ▪ Patellar Reamer Guide ▪ Patellar Resurfacing Reamer ▪ Patellar Reamer Shaft ▪ Patellar Reamer Depth Stop ▪ Caliper

Surgical Step	Details	Instruments
16. Patellar Resection (Option 2)	▪ Using the Caliper, measure the thickness of the patella. ▪ Adjust the height of the flat plate to the thickness of bone to remain after resection. ▪ Place the Resection Guide arms around the medial and lateral sides of the patella and with the flat plate against the anterior side of the patella. ▪ Clamp the Guide teeth into the patella and secure closed with the threaded nut. ▪ Resect the patella through the saw slot of the Guide then remove the Guide. ▪ Use the Drill Guides to determine the diameter of the patella desired. ▪ Assembly the appropriate sized Patellar Drill Guide over the Patellar Clamp. ▪ Position the Drill Guide over the resected surface of the patella and secure the Clamp closed with the threaded nut. ▪ Use the Patellar Peg Drill to prepare the three holes through the Guide then remove the Clamp and Drill Guide.	▪ Caliper ▪ Resection Guide ▪ Patellar Clamp ▪ Patellar Drill Guide ▪ Patellar Peg Drill
17. Patellar Reduction	▪ Position the appropriate sized and style Patellar Trial on the prepared surface of the patella.	▪ Patellar Trial
18. ROM Assessment	▪ With all of the trials in position, perform a range of motion assessment and balance the soft tissues as necessary.	
19. Trial Removal	▪ Remove the PS Box Trial from the Femoral Trial using a towel clamp. ▪ Remove the Femoral Trial using the Femoral Trial Extractor. ▪ Remove the Tibial and Insert trials using an Osteotome to lift the components out of the knee. ▪ Remove the Patellar Trial using a towel clamp.	▪ Femoral Trial Extractor

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

Surgical Step	Details	Instruments
20. Implantation	▪ After applying cement to the resected surfaces, use the Tibial Baseplate Impactor to secure the Tibial Baseplate Implant to the tibia. ▪ Assembly the anterior and posterior cam arms of the Femoral Impactor to the Femoral Implant. Secure the Femoral Implant by tightening the knob. ▪ Position the proximal aspect of the posterior condyles against the resected bone and then rotate the Femoral Impactor anteriorly until all of the resected surfaces are flush. ▪ Use the Articular Impactor to assemble the Articular Insert Implant into the locking mechanism of the Tibial Baseplate Impant. ▪ Position the Patellar Implant onto the prepared patellar surface and secure its position with the Patellar Cement Clamp by tightening the threaded nut.	▪ Femoral Impactor ▪ Tibial Baseplate Impactor ▪ Articular Impactor ▪ Patellar Cement Clamp

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

FEMOROTIBIAL ROTARY CONSTRAINT OF THE HIGH PERFORMANCE TOTAL KNEE SYSTEM AT 0°, 90°, AND 120° OF SIMULATED FLEXION

By:
Josh Stapleton

Orthopaedic Research Report - OR-04-138
September 2004

Smith & Nephew, Inc.
Memphis, Tennessee

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

FEMOROTIBIAL CONTACT AREA ANALYSIS OF THE HIGH PERFORMANCE TOTAL KNEE SYSTEM

By
Josh Stapleton and Bob Jones

Orthopaedic Research Report OR-04-144
September 2004

Smith & Nephew, Inc.
Memphis, Tennessee

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

PATELLOFEMORAL CONTACT AREA ANALYSIS OF THE HIGH PERFORMANCE TOTAL KNEE SYSTEM

by
Josh Stapleton

Orthopaedic Research Report - OR-04-142
September 2004

Smith & Nephew, Inc.
Memphis, Tennessee

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

A/P Static and Fatigue Testing of the High Performance Knee System Tibial Insert

by

Stanley Tsai and Patrick Aldinger

Orthopaedic Research Report OR-04-129
August 2004

Smith & Nephew, Inc.
Memphis, Tennessee

215

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

PATELLO-FEMORAL RESISTANCE TO LATERAL SUBLUXATION OF THE HIGH PERFORMANCE KNEE

By:
Bob Jones

Orthopaedic Research Report - OR-04-119
August 2004

Smith & Nephew, Inc.
Memphis, Tennessee

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2016-10402, Released by CDRH on 03-13-2017.

510(k) Premarket Notification Database

Device Classification Name	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer
510(K) Number	K951987
Regulation Number	888.3560
Device Name	GENESIS II TOTAL KNEE SYSTEM
Applicant	SMITH & NEPHEW RICHARDS, INC. 1450 Brooks Rd. Memphis, TN 38116
Contact	Thomas L Craig
Product Code	JWH
Date Received	04/27/1995
Decision Date	08/22/1995
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary Only
Type	Traditional
Reviewed By Third Party	No

Database Updated 9/08/2004

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records Processed under FOIA Request 2016-1040 Released by CDRH on 03-13-2017.

510(k) Premarket Notification Database

Device Classification Name	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer
510(K) Number	K991581
Regulation Number	888.3560
Device Name	NEXGEN COMPLETE KNEE SOLUTION LEGACY POSTERIOR ST
Applicant	ZIMMER, INC. P.O. Box 708 Warsaw, IN 46581 0708
Contact	Stephen Mckelvey
Product Code	JWH
Date Received	05/07/1999
Decision Date	07/30/1999
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 9/08/2004

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

K991581

30

zimmer

P.O. Box 708
Warsaw, IN 46581-0708
219 267-6131

510(k) Summary of Safety and Effectiveness
***NexGen*® Complete Knee Solution *Legacy*® Posterior Stabilized (LPS);**
LPS-Flex Fixed Bearing Femoral and Articular Surface Components

I. Submitted by:

Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

II. Contact Person:

Stephen H. McKelvey
Senior Regulatory Affairs Associate
Regulatory Affairs
Telephone: (219) 372-4944
Facsimile: (219) 372-4605

III. Date Prepared:

May 6, 1999

IV. Name of Device:

A. Trade Name: Femoral and Articular Surface Knee Components

B. Proprietary Name: *NexGen*® Complete Knee Solution *Legacy*® Posterior Stabilized (LPS); LPS-Flex Fixed Bearing Femoral and Articular Surface Components

C. Common Name: LPS-Flex Fixed Bearing Knee

D. Classification Name and Reference: Knee joint patellofemorotibial polyethylene/metal/polyethylene semiconstrained cemented total knee prosthesis – 21 CFR 888.3560

A Bristol-Myers Squibb Company

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

311

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

K991581

E. Predicate Device:

NexGen® Complete Knee Solution *Legacy*® LPS Knee

F. Device Description:

The LPS-Flex Fixed Bearing Knee is a semiconstrained, condylar system for use without the cruciate ligaments when additional stability is required to prevent anterior subluxation of the femur relative to the tibia in flexion. The LPS-Flex Fixed Bearing Knee consists of an LPS-Flex femoral and an LPS-Flex articular surface.

G. Intended Use:

This device is intended to reduce or relieve pain and restore function and motion to the knee joint. Total knee replacement is indicated for patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery.

The LPS-Flex Fixed Bearing Knee provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range. This device is intended for cemented use only.

H. Comparison to Predicate Device:

See attached table.

I. Non-clinical Performance and Conclusions:

1. The level of constraint for the proposed device was analyzed per ASTM F1223. The femoral-to-articular surface motion is resisted by the articulating surface geometry, the polyethylene spine and the close conformity between the two components. The simulation exhibited negligible displacement variances between the LPS-Flex and the predicate device. Constraint was not significantly different.

2. The contact area was also determined and showed an increase in conformity for the device as compared to the predicate.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

K991581

3. The tibial baseplate interlock mechanism for the device is the same as the predicate device. A screw is added to some LPS-Flex articular surfaces to enhance fixation during high flexion.

4. No additional fatigue strength data was needed because the device uses the predicate tibial baseplate.

J. Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

K 991581

Technological Comparison to Predicate Device

Parameter	Identical, Similar or Different?	Similarities and Differences
Design	Similar	• Frontal plane conformity between the femoral and articular surface components is identical. The LPS-Flex femoral has a modified sagittal plane as compared to the predicate. This gives the LPS-Flex increased conformity during walking gait angles of flexion and accommodates the extended flexion range. • Compatibility between predicate and LPS-Flex components is high (predicate femorals can be used with the LPS-Flex articular surface). • The patellar groove design is identical for the predicate and LPS-Flex device. The same patella is used for both devices. • One additional posterior femoral bone cut is required to accommodate the extended flexion range of the LPS-Flex, otherwise the box and patellar groove geometries are the same as the predicate and standard *NexGen* instrumentation may be used. • To improve stability of the femoral component on the articular surface and to reduce the moment applied to the polyethylene spine, the shape of the femoral cam was modified and the clearance posterior to the polyethylene spine was deepened. This improves resistance to subluxation beyond the predicate and provides for the correct rollback and kinematics of the LPS-Flex joint. The cam and spine geometries of the LPS-Flex were also designed to provide a low cam/spine contact which reduces the bending load on the spine during high load flexion activities, such as squatting.
Materials	Similar	• Femoral component is *Zimaloy*® Cobalt-Chromium-Molybdenum Alloy for both the predicate and LPS-Flex. • Articular surface is UHMWPE for both the predicate and LPS-Flex. A *Tivanium insert* is added to the LPS-Flex. • Surface characteristics are identical for both the predicate and LPS-Flex (Uncoated, PMMA coated and *Conidium* hardened).
Performance	Similar	• Interlock mechanism – 17 and 20 mm thick LPS-Flex articular surfaces require a secondary screw fixation, in addition to the dovetail locking system already present in the predicate and LPS-Flex. This screw provides an additional safety factor to prevent anterior lift-off of the articular surface from the tibial baseplate. • Tibial Baseplate Fatigue Strength – The LPS-Flex knee uses the predicate tibial baseplate and has the same fatigue strength. • Lateral Stability of the Patellofemoral Joint – The patellar groove design and stability of the LPS-Flex femoral component is the same as the predicate. Both are used with all-polyethylene patellar components. • Wear Data –The LPS-Flex has a minimum polyethylene thickness of 6.5 mm. Even though the LPS-Flex increases the maximum active flexion angle to 155 degrees, the design has maintained the conformity necessary to minimize or eliminate any new movement mechanisms that could affect wear.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Parameter	Identical, Similar or Different?	Similarities and Differences
Sterility	Identical	• There are no differences between the predicate and LPS-Flex sterility processes. Both are terminally sterilized by gamma radiation. Gamma radiation processing and dose mapping are conducted according to ANSI/AAMI/ISO 11137-1994. The products are accepted for release as sterile though a validated dosimetric release program designed to provide a sterility assurance level (SAL) of 10^{-6} or better (ANSI/AAMI/ISO 11137-1994, ANSI/AAMI ST32-1991 and ISO/TR 13409-1996).
Biocompatibility	Identical	• Material specifications for both the predicate and LPS-Flex meet or exceed ASTM standards, are common to orthopaedic products today and do not require additional biocompatibility testing.
Pyrogenicity	Identical	• Neither the predicate or the LPS-Flex are labeled as nonpyrogenic. Per USP XXIII, NF18 (1995 edition), page 1719, "These requirements do not apply to orthopaedic products."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 1999

Mr. Steven H. McKelvey
Senior Regulatory Affairs Associate
Zimmer Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K991581
Trade Name: NexGen Complete Knee Solution Legacy Posterior Stabilized (LPS)- Flex Fixed Bearing Femoral and Articular Surface Components
Regulatory Class: II
Product Code: JWH
Dated: May 6, 1999
Received: May 7, 1999

Dear Mr. McKelvey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General Regulation (21 CFR Part 820), and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

Indications for Use

510(k) Number (if known): K991581

Device Name:

NexGen® Complete Knee Solution *Legacy*® Posterior Stabilized (LPS); LPS-Flex Fixed Bearing Femoral and Articular Surface Components

Indications for Use:

This device is intended to reduce or relieve pain and restore function and motion to the knee joint. Total knee replacement is indicated for patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery.

The LPS-Flex Fixed Bearing Knee provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range. The LPS-Flex femoral, when used with LPS-Flex articular surfaces, is designed for use with both cruciate ligaments excised and when load bearing range of motion (ROM) is expected to be less than or equal to 155 degrees. This device is intended for cemented use only.

(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 Devices
510(k) Number K991581

Prescription Use X
(Per 21 CFR 801.109)

OR Over-the-Counter Use ____
(Optional Format 1-2-96)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b) (5)

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Peter Allen

Subject: 510(k) Number K042515/S1

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

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

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

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

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

☐ The required certification and summary for class III devices

☑ The indication for use form

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

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

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

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

Predicate Product Code with class: JWH, II

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

Review (Branch Chief) John Hold (Branch Code) ORDB (Date) 3/9/05

Final Review (Division Director) Mark N Melkerson (Date) 3/11/05

Revised:4/2/03

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

Standards Data Form for Abbreviated 510(k)s

510(k) Number: K042515

Standard Organization No:
or
Standard Identification No:
or
CDRH Internal Reference No:

The sponsor did not rely on a recognized standard but on a guidance document entitled, "*Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-Constrained Total Knee Prostheses*", dated April 1993.

Declaration of Conformity Elements:

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

Was there another standard used in the review of this submission? yes no

If another standard was used, please fill out an additional form.

* This is not the third party that reviews 510ks

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

510(k) MEMORANDUM

TO: **K042515/S001**
FROM: Peter G. Allen, Biomedical Engineer, M.S.
FDA/CDRH/ODE/DGRND/Orthopedic Devices Branch
DATE: March 3, 2005
SUBJ: **Smith & Nephew High Performance Knee**
Product Code: JWH; CFR 888.3560; 87, Class II
FIRM: **Smith & Nephew, Inc.**
Contact: Janet Johnson Akil, Director, Regulatory Affairs
Phone: (901) 399-5520 Fax: (901) 398-5146
e-mail: janet.akil@smith-nephew.com

Recommendation: Based on the similar technological characteristics, materials, design, sizes, and intended use, I recommend that the subject device be found **SE** to the legally marketed predicate devices.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]

Peter G. Allen, Biomedical Engineer
DGRND/ORDB
March 3, 2005

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?	N/A	
4. If, not, has POS been notified?		
5. Is the product a device?	✓	✓
6. Is the device exempt from 510(k) by regulation or policy?	✓	
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	N/A	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 042515

Reviewer: Peter Allen

Division/Branch: DGRUD/ORDB

Device Name: Smith & Nephew High Performance Knee

Product To Which Compared (510(K) Number If Known): K946088, K951987, K032295

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		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?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		✓	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: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

See Review Memo

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

1. Intended Use: See Memo

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

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 performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Peter Allen

Subject: 510(k) Number K 042515

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

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

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

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

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

☐ The required certification and summary for class III devices

☑ The indication for use form

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

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

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

☐ No Confidentiality ☐ Confidentiality for 90 days ☑ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: JWH, II

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

Review: ORDB 12/1/04
(Branch Chief) (Branch Code) (Date)

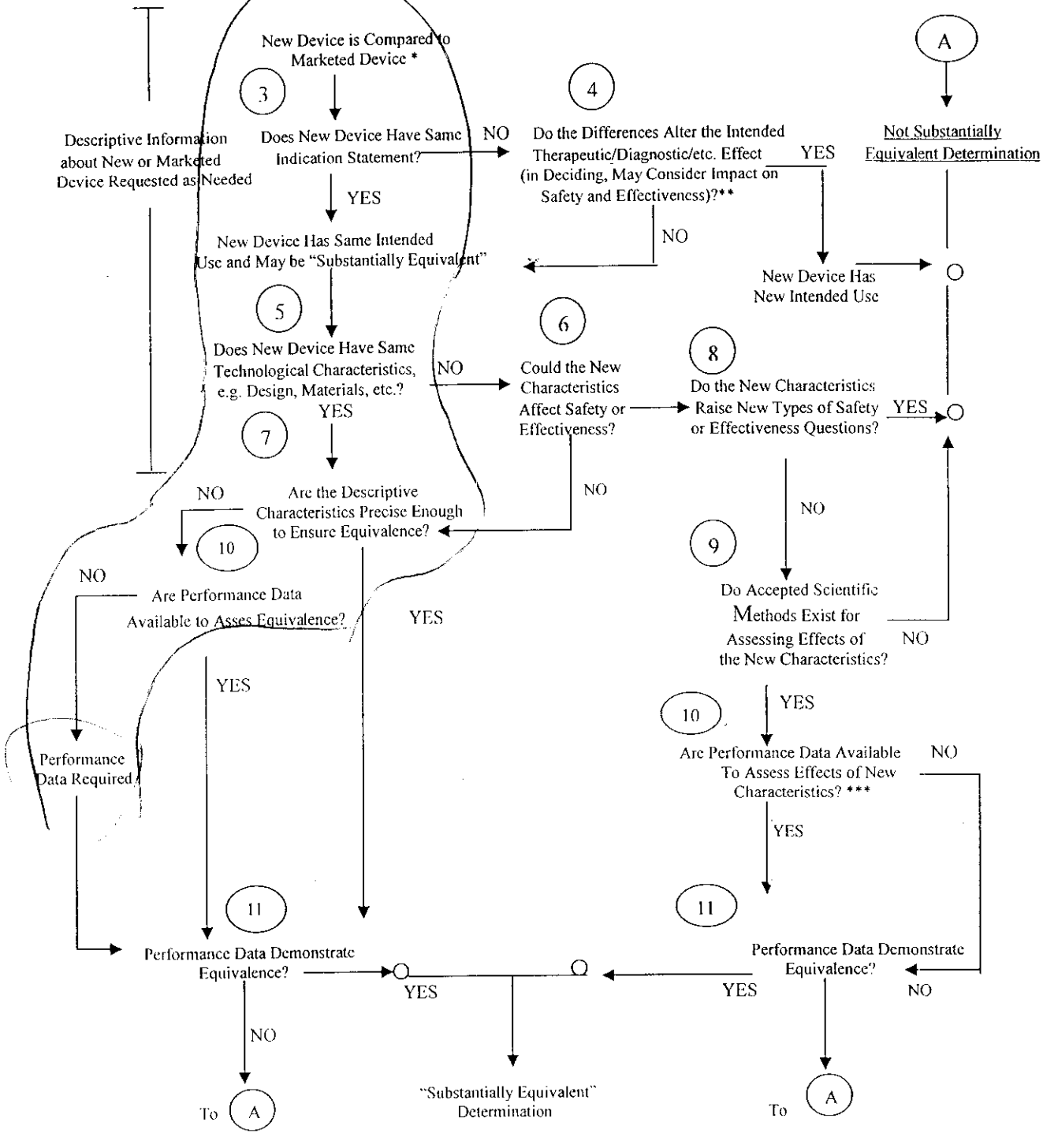
Final Review: for Marsha A. Mullerson 12/1/04
(Division Director) (Date)

Revised:4/2/03

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

510(k) MEMORANDUM

TO: **K042515**
FROM: Peter G. Allen, Biomedical Engineer, M.S.
FDA/CDRH/ODE/DGRND/Orthopedic Devices Branch
DATE: November 29, 2004
SUBJ: **Smith & Nephew High Performance Knee**
Product Code: JWH; CFR 888.3560; 87, Class II
FIRM: **Smith & Nephew, Inc.**
Contact: Janet Johnson Akil, Director, Regulatory Affairs
Phone: (901) 399-5520 Fax: (901) 398-5146
e-mail: janet.akil@smith-nephew.com

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]

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[redacted]

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(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

Peter G. Allen, Biomedical Engineer
DGRND/ORDB
November 29, 2004

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?	N/A	
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	mm	
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	N/A	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K042515

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☐ Special 510(k) - Do Sections 1 and 2

☒ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. 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.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
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. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)	✓	
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.**]		

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For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.	↓	

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	↓	
b) Sterilization and expiration dating information:		
i) sterilization process	↓	
ii) validation method of sterilization process	↓	X
iii) SAL	↓	X
iv) packaging	↓	X
v) specify pyrogen free	↓	
vi) ETO residues		X
vii) radiation dose	↓	
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening X **Yes** ____ **No**
Reviewer: Peter Allen
Concurrence by Review Branch:_____

Date:_____

104

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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REVISED:3/14/95

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"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 042515

Reviewer: Peter Allen

Division/Branch: DGRND/ORDB

Device Name: High Performance Knee

Product To Which Compared (510(K) Number If Known): K946088, K951987, K032295

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		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?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		✓	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: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation. See memo

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

See Memo

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

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 performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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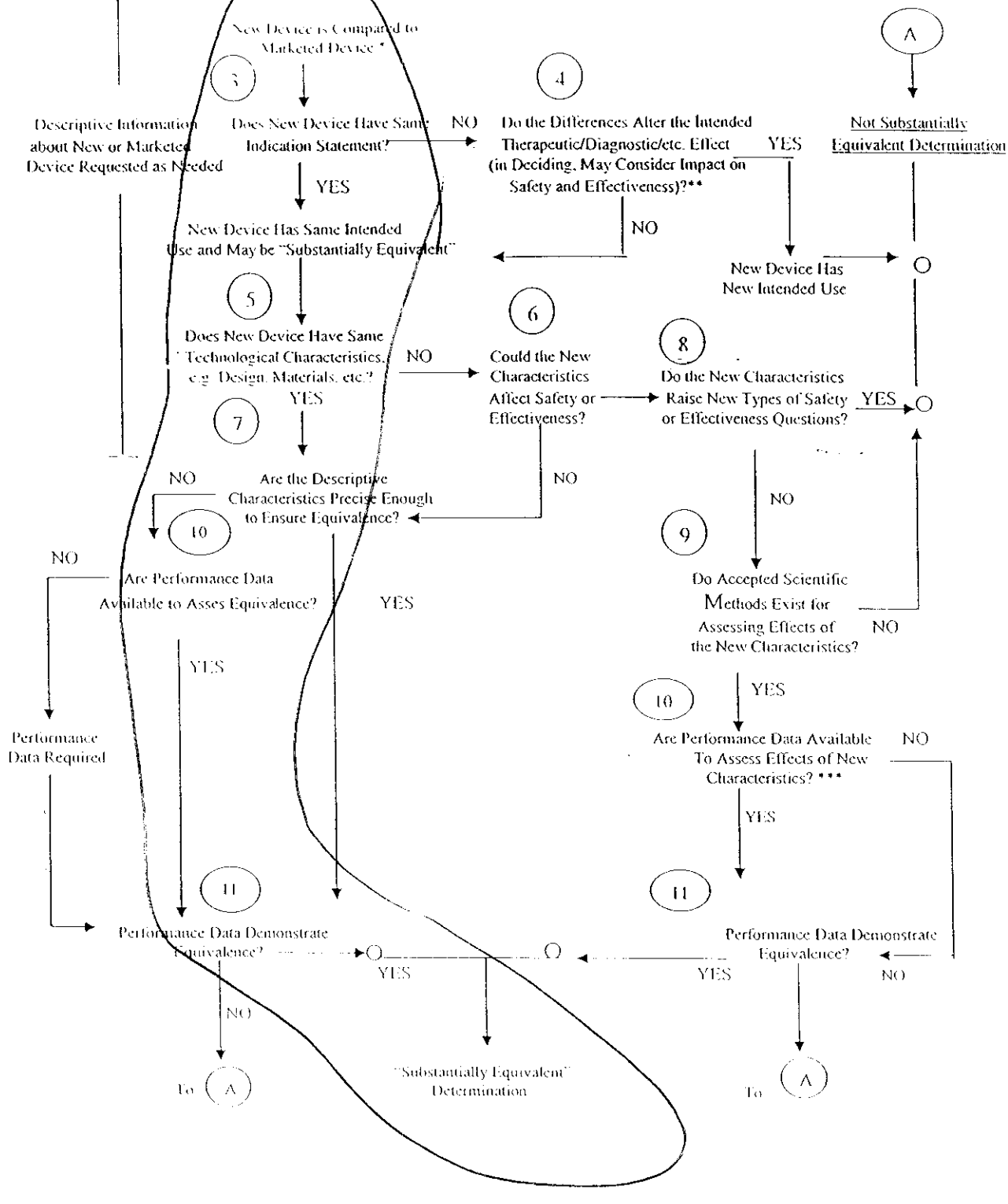
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



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

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

March 02, 2005

SMITH & NEPHEW, INC.
ORTHOPAEDIC DIVISION
1450 E. BROOKS RD.
MEMPHIS, TN 38116
ATTN: JANET JOHNSON AKIL

510(k) Number: K042515
Product: SMITH & NEPHEW, INC. HIGH PERFORMANCE KNEE

The additional information you have submitted has been received.

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

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-16-2017. K042515/S1

We are smith&nephew

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

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

March 1, 2005

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

Attn: Peter Allen

RE: K042515 – Abbreviated 510(k) for the *Smith & Nephew High Performance Knee*

Dear Mr. Allen:

Pursuant to a letter from the Food and Drug Administration dated December 1, 2004, during which FDA requested clarification and/or additional information relevant to 510(k) K042515, we are providing the following information and documentation via FedEx. Please refer to **Exhibit 1** to review a copy of the FDA letter containing the questions that we received regarding Abbreviated 510(k) K042515.

(b)(4) Confidential and Proprietary Information

[redacted]

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21

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]

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[redacted]

We believe the above clarification, together with the supporting documentation, is responsive to the questions. However, if you have further questions, or require additional information, please contact me directly at 901-399-5520 or via email at jason.sells@smithnephew.com as soon as possible.

We appreciate your working with us to resolve these issues quickly.

Sincerely,

Jason Sells
Regulatory Affairs Specialist

Enclosures

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 - 2004

DEC 2004
REGULATORY AND CLINICAL AFFAIRS

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

Re: K042515
Trade Name: Smith & Nephew High Performance Knee
Dated: September 15, 2004
Received: September 16, 2004

Dear Ms. Akil:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information.

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/cdrh/modact/leastburdensome.html

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff 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. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-10402; Released by CDRH on 03-13-2017.

If you have any questions concerning the contents of the letter, please contact Mr. Peter Allen at (301) 594-2036, extension 157. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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ANTERIOR / POSTERIOR DRAW AND ROTARY LAXITY CONSTRAINT TESTING OF THE GENESIS II HIGH FLEX P/S AND HIGH PERFORMANCE KNEE SYSTEMS

By:
Bob Jones

Orthopaedic Research Report - OR-05-30
February 2005

Smith & Nephew, Inc.
Memphis, Tennessee

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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SUMMARY REPORT

Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-Constrained Total Knee Prostheses

(dated April 1993)

Smith & Nephew High Performance Knee

This Summary Report describes how the applicable guidance document was used during device development and testing to address the risks associated with the subject devices.

(b)(4) Confidential and Proprietary Information

[redacted]

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(b)(4) Confidential and Proprietary Information and (b)(5)

Pete Allen, M.S.
Biomedical Engineer
Orthopedic Devices Branch
FDA/CDRH/ODE/DGRND

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Orthopaedics
Smith & Nephew
1450 Brooks Rd
Memphis, TN 38116
USA

T 901.399-5146
F 901-399-6020
www.smith-nephew.com

We are smith&nephew

To Jason Sells

From Stanley Tsai

Date January 31, 2005

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[redacted]

TM

SMITH & NEPHEW CONFIDENTIAL

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We are smith&nephew

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