NOV 2 5 2008

510(k) Summary
Smith & Nephew, Inc. Patient Matched Cutting Blocks

Submitter's Name:	Smith & Nephew, Inc., Orthopaedic Division
Submitter's Address:	1450 Brooks Road, Memphis, TN 38116
Submitter's Telephone Number:	901-399-5340
Contact Person:	Megan Bevill
Date Summary Prepared:	November 17, 2008
Trade or Proprietary Device Name:	Patient Matched Cutting Blocks
Common or Usual Name:	Knee Prosthesis
Classification Name:	21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics 87/JWH, MBH

Device Description

Subject of this premarket notification are Smith & Nephew's Patient Matched Cutting Blocks. The Patient Matched Cutting Blocks are designed and manufactured from patient imaging data (MRI, CT, X-Ray).

Intended Use and Indications

Smith & Nephew's Patient Matched Cutting Blocks are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting.

The Patient Matched Cutting Blocks are intended for use with existing Smith & Nephew, Inc. knee systems and their cleared indications for use.

The Patient Matched Cutting Blocks are intended for single use only.

Substantial Equivalence

The design and intended use of the Patient Matched Cutting Blocks are substantially equivalent to Smith & Nephew, Inc.'s distal femoral and proximal tibial cutting blocks which are used in conjunction with the Smith & Nephew, Inc. implant systems identified in the table below.

System	510(k)	Clearance Date
Genesis II Knee System	K951987 K962137 K962557 K030612 K032683	8/22/1995 8/2/1996 12/5/1996 5/27/2003 8/28/2003
Legion Knee System	K073325	12/20/2007
Journey BCS Knee System	K042515	3/14/2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Smith & Nephew, Inc.
% Ms. Megan Bevill
1450 East Brooks Road
Memphis, Tennessee 38116

APR 15 2011

Re: K082358
Trade/Device Name: Patient Matched Cutting Blocks
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: OOG, JWH, MBH
Dated: November 14, 2008
Received: November 18, 2008

Dear Ms. Bevill:

This letter corrects our substantially equivalent letter of November 25, 2008.

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 (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

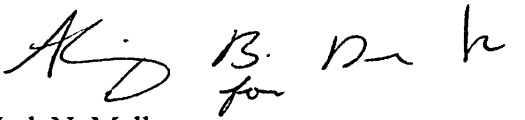
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K082358

Device Name: Smith & Nephew, Inc. Patient Matched Cutting Blocks

Indications for Use:

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K082358