K080875

Smith & Nephew, Inc.
Summary of Safety and Effectiveness
PiGalileo 4th Generation System

JUL 18 2008

Contact Person and Address
Rishi Sinha
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Reconstruction
1450 Brooks Road
Memphis, TN 38116
(901)399-6054

Date of Summary: 06/30/2008

Name of Device: PiGalileo 4th Generation System
Common Name: PiGalileo

Device Description
The PiGalileo 4th Generation Navigation System is a software-controlled electromechanical sterotaxic device for computer aided navigation of PiGalileo surgical instruments with the purpose of assisting the surgeon in optimally positioning knee and hip prostheses during total knee and hip arthroplasties.

The subject device incorporates new hardware components as well as new platform system software. The PiGalileo 4th Generation System allows for existing knee and hip software applications to run on the new platform system.

Device Classification

21 CFR 882.4560 Stereotaxic Instrument – Class II

Indications for Use
The PiGalileo 4th Generation System is intended for use as a stereotaxic instrument to assist in the positioning of total knee and total hip replacement components intra-operatively. The system is a computer controlled image guided system equipped with a three-dimensional tracking sub-system. The PiGalileo System is intended to assist the surgeon in determining reference alignment axes in relation to anatomical landmarks, as such instruments are precisely positioned relative to these axes by displaying their locations. This allows for accurate positioning of instruments used for total knee and total hip replacement surgery and provides intraoperative measurements of bone alignment.

Substantial Equivalence Information

The overall design of the Smith & Nephew PiGalileo 4th Generation System is substantially equivalent to previously cleared devices listed below.

Manufacturer	Description	510(k)	Clearance Date
PLUS Orthopedics AG	PiGalileo Total Knee Replacement (TKR) System	K061362	10/06/06
PLUS Orthopedics AG	PiGalileo Total Hip Replacement (THR) System	K070731	7/31/07

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2008

Smith & Nephew, Inc.
% Rishi Sinha
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

Re: K080875
Trade/Device Name: PiGalileo 4th Generation
Regulation Number: 21 CFR 882.4560
~~Regulation Name: Stereotaxic instrument~~
Regulatory Class: II
Product Code: HAW
Dated: June 30, 2008
Received: July 1, 2008

Dear Rishi Sinha:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K080875

Device Name: PiGalileo 4th Generation

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)

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

510(k) Number K080875