K081232

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AUG - 6 2008

510(k) Summary
for
TOTAL KNEE SURGETICS Navigation System with Praxiteles

1. Submitter Name and Address:

Praxim
"Le Grand Sablon"
4, Avenue de l'Obiou
38 700 La Tronche
France

Contact Name: Annie Pollier
Telephone: (0033) 4 76 54 95 03

Date Prepared: April 25th 2008

2. Device Name:

Proprietary Name: TOTAL KNEE SURGETICS Navigation System with Praxiteles
Common/Usual Name: Image guided surgical navigation system
Classification Name: Computed tomography x-ray system (accessory)

2. Equivalent to:

510(k) number	K060282	K061362	K063408
Proprietary Name	PRAXIM	PLUS ORTHOPEDICS AG	PRAXIM
Common/Usual Name	TOTAL KNEE SURGETICS Navigation System	PIGALILEO TOTAL KNEE REPLACEMENT (TKR) SYSTEM	CTLOGICS Navigation System
Classification Name	instrument, stereotaxic	instrument, stereotaxic	instrument, stereotaxic

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4. Intended Use:

The TOTAL KNEE SURGETICS NAVIGATION SYSTEM WITH PRAXITELES is intended for use during stereotaxic surgery to aid the surgeon in locating anatomical structures and aligning the endoprostheses with the anatomical structures.

It is specifically indicated for:

- Total Knee Arthroplasty

5. Device Description:

As the equivalent TOTAL KNEE SURGETICS NAVIGATION SYSTEM, the TOTAL KNEE SURGETICS NAVIGATION SYSTEM WITH PRAXITELES consists of the following major components and subsystems:

- The Station (Surgetics or NanoStation), consisting of a mobile computer system and an optical localizer
- Ancillary instruments, specific motorized cutting block and reflective markers used for reference and registration
- TOTAL KNEE SURGETICS with Praxiteles software

The main modification to the predicate device K060282 concerns the use of a new motorized cutting block PRAXITELES®.

6. Technological Characteristics and Substantial Equivalence

The underlying technology of the TOTAL KNEE SURGETICS Navigation System with PRAXITELES is the same as for the predicate device K060282. The system is based on the same operating principle and control mechanism to provide the user with the same kind of information and guidance for the same surgery. The main changes with respect to the predicate device concern the addition of a motorized cutting block Praxiteles. Praxiteles is a motorized cutting block controlled by the navigation system that automatically positions the cutting slot to the desired cut. Then the position of the motorized cutting block is controlled and the surgeon can proceed to the cut as it is done in the conventional way. The system enables the cutting slot to be positioned either automatically or manually.

7. Performance Testing

The TOTAL KNEE SURGETICS Navigation System with Praxiteles was tested in a non clinical setting (bench testing, specimen) to assess that no new safety and efficiency issues were raised in the device. Analyses show that the accuracy and performance of the system was adequate for its intended use and not reduced in comparison to the predicate device.

In conclusion the modified device TOTAL KNEE SURGETICS Navigation System with Praxiteles is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2008

Praxim
% Ms. Annie Pollier
VP, Operations, Quality & Regulatory
Le Grand Sablon
4, Avenue dc l'Obiou
38 700 La Tronche
France

Re: K081232
Trade/Device Name: TOTAL KNEE SURGETICS Navigation System with Praxiteles
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: July 10, 2008
Received: July 17, 2008

Dear Ms. Pollier:

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

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STATEMENT OF INDICATIONS FOR USE

TOTAL KNEE SURGETICS Navigation System with Praxiteles

510(k) Number (if known): K081232

Device Name: TOTAL KNEE SURGETICS Navigation System with Praxiteles

The TOTAL KNEE SURGETICS Navigation System with Praxiteles is intended for use during stereotaxic surgery to aid the surgeon in locating anatomical structures and aligning the endoprostheses with the anatomical structures.

It is specifically indicated for :

* Total Knee Arthroplasty

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

510(k) Number K081232

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