510(k) Summary
for
TOTAL HIP SURGETICS Navigation System K072267

1. Submitter Name and Address:

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

DEC 1 0 2007

Contact Name: Mady BATAILH
Telephone: (0033) 4 76 54 95 03

Date Prepared: August 7th, 2007

2. Device Name:

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

3. Equivalent to:

K060468 – VectorVision Hip – BrainLAB AG
K060282 – TOTAL KNEE SURGETICS Navigation System – PRAXIM S.A.

4. Intended Use:

The TOTAL HIP SURGETICS Navigation System is an optically based surgical navigation system. It is intended for use during stereotaxic surgery to aid the surgeon in locating anatomical structures.

5. Indications for use

The system is indicated for any medical condition in which the use of stereotaxic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the pelvis, the femur can be identified by acquiring multiple landmarks.

Example procedures include but are not limited to:

Hip arthroplasty

6. Device Description:

As the equivalent TOTAL KNEE SURGETICS navigation system, the TOTAL HIP SURGETICS navigation system consists of the following major components and subsystems:

- The Navigation Station, consisting of a mobile computer system and an optical localizer
- Ancillary instruments and reflective markers used for reference and registration
- TOTAL HIP SURGETICS software

7. Technological Characteristics and Substantial Equivalence

The TOTAL HIP SURGETICS Navigation System is substantially equivalent to other stereotaxic instruments that have been cleared for use in orthopedic surgery, including the BrainLab VectorVision Hip and the PRAXIM TOTAL KNEE SURGETICS Navigation Systems. The TOTAL HIP SURGETICS Navigation system and the predicate systems all acquire positional data by tracking reflective markers and digitizing the relative locations of anatomical landmarks, to aid the surgeon in linear procedures. It allows the surgeon to locate surgical instruments' position in regards to anatomical landmarks. The system uses an infrared camera for localization and guidance of surgical instruments during the procedure.

The underlying technology of the TOTAL HIP SURGETICS Navigation System is the same as the TOTAL KNEE SURGETICS Navigation system. The system is based on the same operating principle and control mechanism to provide the user with the same kind of information and guidance.

8. Performance Testing

The TOTAL HIP SURGETICS Navigation System was tested to assess that no 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 devices. In conclusion the TOTAL HIP SURGETICS Navigation System is substantially equivalent to the VectorVision Hip #K060468 and the TOTAL KNEE SURGETICS Navigation System #K060282.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2007

Praxim SA
% Mady Batailh
Quality & Regulatory Affairs
Director
Le Grand Sablon
4, avenue de l'Obiou
38700 LA Tronche
France

Re: K072267
Trade/Device Name: TOTAL HIP SURGETICS Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: November 13, 2007
Received: November 23, 2007

Dear Mady Batailh:

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

STATEMENT OF INDICATIONS FOR USE

TOTAL HIP SURGETICS Navigation System

510(k) Number (if known): K072267

Device Name: TOTAL HIP SURGETICS Navigation System

Indications for Use:

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Example procedures include but are not limited to:

Hip arthroplasty

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)

(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K072267