K062146

510(k) Summary

AUG 2 1 2006

for

UNI KNEE SURGETICS Navigation System

1. Submitter Name and Address:

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

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

Date Prepared: July 17th, 2006

2. Device Name:

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

3. Equivalent to:

K031196 - Surgetics ORTHO KNEELOGICS Navigation System
K060282 – TOTAL KNEE SURGETICS Navigation System

4. Intended Use:

The UNI KNEE SURGETICS Navigation System 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 :

- UniKnee Arthroplasty

5. Device Description:

As the equivalent Surgetics ORTHO KNEELOGICS Navigation System and TOTAL KNEE SURGETICS Navigation System, the UNI KNEE SURGETICS navigation System consists of the following major components and subsystems:

- The Surgetics Station or the NanoStation, consisting of a mobile computer system and an optical localizer
- Ancillary instruments and reflective markers used for reference and registration
- UNI KNEE SURGETICS software

The main modifications to the predicate devices concern the internal architecture of the software, allowing more easily to integrate new implants and to better adapt the workflow to different surgical techniques. New instruments adapted to new implants are also incorporated.

6. Technological Characteristics and Substantial Equivalence

The underlying technology of the UNI KNEE SURGETICS Navigation System is the same as for the predicate devices. 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 software and engineering modifications with regard to easy integration of new implants (modularization). In addition, the software was modified in order to allow easier adaptation of the workflow to the characteristics of each implant and to different surgical techniques. New navigated instruments have been developed also with respect to easier integration of new implants.

7. Performance Testing

The UNI KNEE SURGETICS Navigation System 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 devices. In conclusion the UNI KNEE SURGETICS Navigation System is substantially equivalent to the Surgetics ORTHO KNEELOGICS Navigation System and the TOTAL KNEE SURGETICS Navigation System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2006

Praxim
% Mady Batailh
Quality and Regulatory Affairs Director
Le Grand Sablon
4 Avenue de l'Obiou
38700 La Tronche
France

Re: K062146
Trade/Device Name: UNI KNEE SURGETICS Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: HAW
Dated: July 17, 2006
Received: July 27, 2006

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 Office of Compliance at (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

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

Enclosure

K062146

Indications for Use Statement

for

UNI KNEE SURGETICS Navigation System

510(k) Number (if known):

Device Name: UNI KNEE SURGETICS Navigation System

Indications for Use:

The UNI KNEE SURGETICS Navigation System 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 :

- UniKnee 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K062146