APR 1 0 2006

K053542

510(k) Summary

for

Surgetics ORTHO OSTEOLOGICS navigation system

1. Submitter Name and Address

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

Contact Name: Stéphane Lavallée
Telephone: 33-4 76 54 95 03

Date Prepared: November 15th, 2005

2. Device Name

Proprietary Name:	SURGETICS ORTHO OSTEOLOGICS NAVIGATION SYSTEM
Common/Usual Name:	Image guided surgical navigation system
Classification Name:	Stereotaxic Instrument: 21 CFR 882.4560, Class II

3. Predicate Device

PRAXIM – Surgetics ORTHO KNEELOGICS navigation system (K 031196)
BrainLab —VectorVision® Osteotomy (K 042513)

4. Intended Use

The *Surgetics ORTHO OSTEOLOGICS navigation system* is an optically based surgical navigation system. It is intended for use as an aid to the surgeon in tracking bone structures and instruments on a 3D model of the patient's bone which is generated through acquiring multiple landmarks. The system is indicated to assist a surgeon to control the lower limb axis during osteotomy procedures.

Examples of orthopedic surgical procedures include, but are not limited to:

Open wedge osteotomy for the lower limb

Closed wedge osteotomy for the lower limb

5. Device Description

The Surgetics ORTHO OSTEOLOGICS Navigation System consists of the following major components and subsystems:

- The Surgetics Station, consisting of a mobile computer system and an optical localizer
- Ancillary instruments and reflective markers used for reference and calibration.
- HTO Monitoring Software for, but not limited to open and closed wedge osteotomy for the lower limb

6. Technological Characteristics and Substantial Equivalence

The Surgetics ORTHO OSTEOLOGICS Navigation System is substantially equivalent to other stereotaxic instruments that have been cleared for use in spine, orthopedic and traumatology surgery, including the BrainLab Vector Vision Osteotomy and the PRAXIM – Surgetics ORTHO KNEELOGICS navigation system. The ORTHO OSTEOLOGICS 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' tip and direction (e.g. screwdriver, awl). The system uses an infrared camera for localization and guidance of surgical instruments during the procedure.

7. Performance Testing

The Surgetics ORTHO OSTEOLOGICS Navigation System was tested for compliance with electrical safety and electromagnetic compatibility standards. In addition, summaries of accuracy testing using phantoms, specimen bench testing, and clinical experience with the system were provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 2006

Praxim S.A.
c/o Medical Device Consultants, Inc.
Mr. Randy Veale
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K053542
Trade/Device Name: Ortho Osteologics navigation system
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: February 27, 2006
Received: March 6, 2006

Dear Mr. Veale:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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): K053542

Device Name: Surgetics ORTHO OSTEOLOGICS navigation system

Indications for Use:

The *Surgetics ORTHO OSTEOLOGICS navigation system* is an optically based surgical navigation system. It is intended for use as an aid to the surgeon in tracking bone structures and instruments on a 3D model of the patient's bone which is generated through acquiring multiple landmarks. The system is indicated to assist a surgeon to control the lower limb axis during osteotomy procedures.

Examples of orthopedic surgical procedures include, but are not limited to:
Open wedge osteotomy for the lower limb
Closed wedge osteotomy for the lower limb

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