K061362

E.0 Premarket Notification 510(k) Summary

OCT - 6 2006

E.1 Submitter Information

Company Name and Address:

PLUS ORTHOPEDICS AG
Erlenstraße 4a
CH-6343 Rotkreuz
Switzerland

Contact Name:

Pamela J. Weagraff, Principal Consultant
Quintiles Consulting
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Norfolk, MA 02056

Telephone: 508-528-1745
Facsimile: 978-752-1225

Date Prepared: May 8, 2006

E.2 Name of Device

2.1 Trade Name: PiGalileo™ Total Knee Replacement (TKR) System (PiGalileo™ Navigation (NAV) TKR Computer-Assisted Surgery (CAS) System)

2.2 Common Name: Navigation System

2.3 Classification Name: Stereotaxic instrument

E.3 Substantial Equivalence Claimed to Predicate Devices

3.1 Galileo CAS/NAV TKR System, K020298, cleared May 2, 2002

3.2 OrthoPilot® 2 Navigation Platform, K003347, cleared February 23, 2001, and K013569, cleared April 4, 2002

3.3 Navitrack™ System – Optical TKR CT-Less, K021760, cleared August 27, 2002, and K 043536, cleared January 14, 2005

E.4 Device Description

The PiGalileo™ Navigation (NAV) Total Knee Replacement (TKR) Computer Assisted Surgical (CAS) System (PiGalileo™ TKR System) is a software-controlled electromechanical sterotaxic device for computer-aided navigation of PI Galileo surgical instruments with the purpose of assisting the surgeon in optimally positioning prostheses of the TC-PLUS and VKS knee systems.

The PiGalileo™ TKR System is based on common stereotaxic technology in which Infrared (IF) LED (light emitting diodes) or passive markers on the surgical instruments allow the instruments to be tracked in real time in the surgical field.

In the case of PiGalileo™ TKR System, patient data that is required to navigate the surgical instruments is collected during the procedure. The system utilizes this data to establish a connection between passive locaters, i.e., Infrared (IF) light, and the system's IF camera as previously described tracks the surgical instruments in real time in the surgical field.

Two passive locators are attached to the tibia and distal femur during surgery, where one locater is mobile to determine specific landmarks, known as Bone Referencing (BR) on the tibia and femur. Once the system has collected the information, the system positions a motorized cutting guide on the femur to support the surgeon during surgery and provides information to position or "navigate" additional instruments.

The surgeon maintains control of the operation and any decisions required with regard to the surgery at all times. Positions of the motorized cutting guide may also be adjusted manually. Risk mitigations were implemented under Design Controls to ensure that sufficient fail safe mechanisms allow the surgeon to convert to non-navigated conventional surgical techniques at any time.

The PiGalileo™ TKR System consists of three main elements:

4.1 System Cart which houses:

- System electronics and cabling
- Monitor
- User Interface
- IF Camera and Camera Stand
- Optional printer

4.2 Software:

- PiGalileo System Software
- Application Software
  a) PiGalileo TKR BR
  b) PiGalileo TKR Ligament Balancing (LB)
  c) PiGalileo TKR Light
  d) PiGalileo TKR Minimally Invasive Surgery (MIS)

4.3 Standard Surgical Instruments and application-specific surgical instruments

E.5 Intended Use

The PiGalileo™ TKR System is intended to be used in computer-assisted orthopedic surgery to aid the surgeon with bone cuts and implant positioning during joint replacement. It provides information to the surgeon that is utilized to place surgical instruments during surgery utilizing anatomical landmarks and other data specifically obtained intra-operatively (e.g., ligament tension, limb alignment, etc.).

Examples of some surgical procedures include but are not limited to:

- Total knee replacement supporting both bone referencing and ligament balancing techniques
- Minimally invasive total knee replacement

E.6 Predicate Device Comparison of Indications for Use / Intended Use and Technical Characteristics

The comparison of the PiGalileo™ TKR System was based on a review of the Design Control documentation for the system, relevant aspects of which are included in the company's 510(k) Premarket Notification, and information concerning the predicate devices that was available to the company internally, i.e., Galileo CAS/NAV TKR System, K020298, and for the other predicate devices via the respective company web sites. Copies of this reviewed information are included at the end of this section. The comparison considered technological characteristics and the indications for use / intended use. Neither bench, animal nor clinical testing were assessed.

E.7 Performance Data

7.1 Performance Standards (Section 514 Compliance): no applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act, for sterotaxic instruments. The PiGalileo™ TKR System does conform to the following FDA recognized standards:

7.1.1 Electromagnetic Compatibility:

IEC 60601-1-2:01: Emissions - Class A Limit

IEC 61000-3-2:01: Harmonics

IEC 61000-3-3:94+A1:01: Voltage Fluctuations

IEC 60601-1-2:01: Immunity

7.1.2 Thermal, Electrical and Mechanical Safety

UL 60601-1: Medical Electrical Equipment Part 1

7.1.3 Software

IEC 60601-1-4:1996, Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems

FDA's "Reviewer Guidance for the Content of Premarket Submission for Software Contained in Medical Devices", May 11, 2005

FDA's "Guidance for Off-The-Shelf Software Use in Medical Devices"

7.1.4 Sterilization

AAMI TIR12:1994, "Designing, testing and labeling reusable medical devices for reprocessing in healthcare facilities".

7.1.5 Risk Analysis

ISO 14971:2000, Application of risk management to medical devices

7.1.6 Biocompatibility (**Note**: applies only to surgical tools, i.e., materials for system and software applications do not come into contact with the patient.)

ASTM/ISO standards for materials that are suitable for surgically invasive devices for transient to short term use.

7.1.7 Performance Testing: Design verification and design validation, e.g., bench testing was performed according to FDA's Design Control Requirements, Title 21 Code of Federal Regulations, Part 820.30.

E.8 **Conclusion**:

The information and data provided in this 510(k) Premarket Notification establish that the PiGalileo™ TKR System is substantially equivalent to the afore-mentioned predicate devices with respect to indications for use/intended use, and technical characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 - 2006

Plus Orthopedics AG
% Quintiles Consulting
Ms. Pamela J. Weagraff, MBA, RAC
Principal Consultant
18 Bridie Lane
Norfolk, Massachusetts 02056

Re: K061362
Trade/Device Name: PiGalileo™ Total Knee Replacement (TKR) System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: September 29, 2006
Received: October 2, 2006

Dear Ms. Weagraff:

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,

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

Enclosure

ODE Indications Statement

510(k) Number (if known): ***Unknown*** K061362

Device Name: PiGalileo™ Total Knee Replacement (TKR) System

Indications for Use:

The PiGalileo™ TKR System is intended to be used in computer-assisted orthopedic surgery to aid the surgeon with bone cuts and implant positioning during joint replacement. It provides information to the surgeon that is utilized to place surgical instruments during surgery utilizing anatomical landmarks and other data specifically obtained intra-operatively (e.g., ligament tension, limb alignment, etc.).

Examples of some surgical procedures include but are not limited to:

- Total knee replacement supporting both bone referencing and ligament balancing techniques
- Minimally invasive total knee replacement

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)

Barbara Buch MD

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

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