K070731

JUL 3 1 2007

Attachment B – Revised Premarket Notification 510(k) Summary

K070731

Premarket Notification 510(k) Summary

1. **Submitter Information**

Company Name and Address:

PLUS ORTHOPEDICS AG
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Switzerland

Contact Name:

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Date Prepared: July 26, 2007

2. **Name of Device**

(a) Trade Name: PiGalileo™ Total Hip Replacement (THR) System

(b) Common Name: Navigation System

(c) Classification Name and Reference:

Title 21 Code of Federal Regulation (CFR), Part 882.4560 Stereotaxic instrument, Product Code: HAW

3. **Substantial Equivalence Claimed to Predicate Device**

VectorVision Hip, K060468, manufactured by BrainLAB AG
Orthopilot® 2 THA V 2.0, K050752, manufactured by Aesculap®, Inc.
Stryker Navigation System, K022365, manufactured by Stryker Corporation
PiGalileo™ Total Knee Replacement (TKR) System, K061362, manufactured by Plus Orthopedics AG

4. **Device Description**

The PiGalileo™ Total Hip Replacement (THR) software application when provided with the PiGalileo™ system cart results in the PiGalileo™ THR System, a software-controlled electromechanical stereotaxic device for computer-aided navigation of PiGalileo™ surgical instruments with the purpose of assisting the surgeon in optimally positioning hip prostheses. Refer to Section 11.0 for an in depth description of the PiGalileo™ THR System.

The PiGalileo™ THR 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.

The PiGalileo™ THR 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™ THR 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.

The precision of navigation–assisted surgery depends on accurate scanning of skeletal landmarks. Scanned morphological data represents the basis for calculating the position of the hip cup and hip stem. Scanned points must represent unique anatomic landmarks so that they can be located in a safe and reproducible manner throughout surgery. For cup navigation, the spinae, left/ right are scanned as well as the symphysis. Each point is scanned three times to enhance precision and used for inclination and anteversion alignment. For stem navigation, the sagital plane is determined from the tibialis anterior and the intersection point on the femur. The position and alignment of the proximal stem axis are determined with a probe which provides the basis of the varus/valgus alignment.

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

The navigation platform for the PiGalileo™ THR System is the same as the navigation platform cleared under PiGalileo™ TKR System, K061362, and includes the following elements:

(a) System Cart housing the following items; there are ***no*** changes to the system cart as compared to K061362.

- System electronics such as CPU and connection box
- Monitor
- User Interface consisting of keyboard, touch pad and hard controls, e.g., "ON / OFF", footswitch
- Infrared (IF) Camera and Camera Stand/Tripod
- Optional printer
- System cabling

(b) PiGalileo™ THR Software refers to the PiGalileo™ System Software and the THR software application:

- PiGalileo™ System Software: this software is the same as that of the PiGalileo™ TKR System; there are ***no*** changes to either the system software or the calculations or the landmark technique as compared to K061362.
- PiGalileo™ THR software application consists of two applets, PiGalileo™ Hip Cup and PiGalileo™ Hip Stem. Each applet consists of a collection of software modules that support the surgeon in hip cup and hip stem replacement. Each module is designed specifically for an implant in which the software calculates the values provided on screen differently for each implant, the specific implant geometry and the implant specific instruments.

(c) Surgical Instruments: include universal instruments such as hemispheres, and various locators; navigated instruments are equipped with markers that are tracked by the stereotaxic camera.
The POLARCUP® Dual Mobility System consists of two components: a thin press fit shell and a liner component.

5. **Intended Use / Indication for Use**

The PiGalileo™ Total Hip Replacement (THR) 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. hip center, pelvic plane etc.).

Examples of some surgical procedures include but are not limited to:
Primary total hip replacement
Revision hip surgery
Minimally invasive hip arthroplasty

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

The comparison of the PiGalileo™ Total Hip Replacement (THR) System to the predicate devices was based on a review of the Design Control documentation, relevant aspects of which are included in the company's 510(k) Premarket Notification, and information concerning the predicate device, PiGalileo™ TKR System, K061362, that was available to the company internally, information concerning the predicate device that was obtained from the predicate device manufacturer's web site. The comparison considered technical characteristics and the indications for use / intended use.

7. **Performance Data**

(a) Performance Standards (Section 514 Compliance): No performance standards applicable to this device, 882.4580, stereotaxic instrument, have been adopted under Section 514 of the Food Drug and Cosmetic Act.

(b) PiGalileo™ Total Hip Replacement (THR) System does conform to the following FDA recognized standards:

i) Thermal, Electrical and Mechanical Safety
IEC 60601-1: Medical Electrical Equipment Part 1: General Requirements for Safety

ii) Electromagnetic Compatibility:
IEC 60601-1-2:01: Electromagnetic Compatibility, Requirements and Tests, Emissions - Class A Limit, and Immunity
IEC 61000-3-2:01: Electromagnetic Compatibility – Part 3-2 Limits for Harmonic Current Emissions
IEC 61000-3-3:94+A1:01: Electromagnetic Compatibility – Part 3-3 Limitation of Voltage Changes, Voltage Fluctuations

iii) 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"

iv) Sterilization
Cleaning, disinfection and sterilization testing was performed according to the following test protocols:
"Microbiological Efficiency Control of the Automated Cleaning and Disinfection Method", AAMI TIR 12-1994, ISO 17664, LM SOP 2-11-01

"Microbiological Efficiency Control of Steam Sterilization (Fractionated Vacuum Procedure)", AAMI TIR 12-1994, ISO 17664, (half-cycle method), AINSI/AAMI/ISO 11134, EN 556-1, AINSI/AAMI ST 67, LM P 2-11-04, LM SOP 2-11-04

v) Risk Analysis: ISO 14971:2000, Application of risk management to medical devices.

vi) Biocompatibility (**Note**: applies only to surgical tools, i.e., materials for system and THR software application do not come into contact with the patient.) ASTM/ISO standards, i.e., suitable for surgically invasive devices for transient to short term use.

vii) General:
FDA's "Deciding When to Submit a 510(k) for a Change to an Existing Device", January 10, 1997
FDA's "Premarket Notification 510(k): Regulatory Requirements for Medical Devices", August, 1995
FDA's Updated 510(k) Sterility Review Guidance K90-1, August 30, 2002

viii) 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.

8. **Conclusion**:

The information and data provided in this 510(k) Premarket Notification establish that the PiGalileo™ Total Hip Replacement (THR) 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

JUL 31 2007

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

Re: K070731
Trade/Device Name: PiGalileo™ Total Hip Replacement (THR) System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: July 11, 2007
Received: July 16, 2007

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* K070731

Device Name: PiGalileo™ Total Hip Replacement (THR) System

Indications for Use:

The PiGalileo™ Total Hip Replacement (THR) 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. hip center, pelvic plane etc.).

Examples of some surgical procedures include but are not limited to:
Primary total hip replacement
Revision hip surgery
Minimally invasive hip arthroplasty

Prescription Use: X AND/OR Over-the-Counter Use: _____
(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)

Mark N Milhem

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

510(k) Number K070731