

NOV 30 2012

TAB 6

510(K) SUMMARY

K121936

| | |
|---------------------------------|--|
| Official Contact | Richard G. Confer Vice President, Regulatory Affairs and Quality Assurance Blue Belt Technologies 2828 Liberty Ave. Pittsburgh, PA 15222 Email: rconfer@bluebeltech.com 412-683-3844 X 106 412-683-6447 |
| Date of Submission | June 29, 2012 |
| Classification Reference | 21 CFR 882.4560 |
| Product Code | OLO |
| Common/Usual Name | Orthopedic Sterotaxic Instrument |
| Proprietary Name | NavioPFS™ |
| Predicate Device(s) | <i>MAKO Surgical Tactile Guidance System v2.0 ("MAKO RIO") (K081867) The Zimmer (ORTHOsoft) Navitrack® System - OS Unicondylar Knee Universal (K071714)</i> |
| Reason for submission | New Device |

Indications for Use

The NavioPFS™ System is intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

The NavioPFS™ System is indicated for use in surgical knee procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be determined. These procedures include unicondylar knee replacement.

Device Description

The NavioPFS™ System is a computer-assisted orthopedic surgical navigation and surgical burring system. The system uses established technologies of navigation via a passive infrared tracking camera to aid the surgeon in establishing a bone surface model for the target surgery and to plan the surgical implant location based on predefined bone landmarks and known configuration of the surgical implant. The NavioPFS™ System then aids the surgeon in executing the surgical plan by using a standard off-the-shelf surgical drill motor and bur (Anspach/Synthes eMax2 plus (K080802) which has been adapted using a tracking system. The surgical bur is located in a handpiece which allows the bur to move within the handpiece. In the NavioPFS™ System the software controls the position of the tip of the surgical bur relative to the end of a guard attached to the handpiece and prohibits the bur from cutting bone as it approaches the planned target surface. As the planned surface is reached the tip of the bur is fully retracted within the guard.

An alternate mode of operation is the speed control mode. In this mode the speed of the bur is controlled and the bur stops as the planned surface is reached. In this mode of operation the bur does not retract into the guard. This mode of operation is useful in shaping posterior surfaces of the condyle as well as placing post holes.

After the bone is prepared the surgeon is prompted to do a trial range of motion (ROM) test. Data collected using the tibial and femoral trackers is displayed as the surgeon moves the knee and limb through a series of flexion, extension and rotational movements. Data is collected from the trackers and displayed in graphical format. This information is for use by the surgeon in determining fit of the implant (either the trial implant or the final implants after cementing) prior to finalization of the procedure.

The NavioPFS™ Computer system maintains a log of the patient data and procedure data. Each entry is date and time stamped. Data log entries include date and time stamp for data line entry, patient and procedure ID, implant ID, step in process and error messages. This data can be archived to a CD upon demand at the end of the procedure.

Summary of technological similarities with predicates

| Summary of Similarities and Differences NavioPFS™, MAKO RIO and Navitrack System – OS Unicondylar Knee Universal | | | |
|---|---|---|---|
| <u>Devices</u> | <u>Blue Belt Technologies</u> <i>NavioPFS™</i> | <u>Predicate A.</u> <i>MAKO Surgical Tactile Guidance System v2.0 ("MAKO RIO") (K081867)</i> | <u>Predicate B.</u> <i>The Zimmer (Orthosoft) Navitrack® System - OS Unicondylar Knee Universal (K071714)</i> |
| <u>Technological Characteristics</u> | <p>The NavioPFS™ System uses a combination of two established technologies to prepare bone for attachment of implant components. The NavioPFS™ uses intraoperative data collection (image free or non-CT data generation) to create a model of the patient's femur and tibia and allows the surgeon to prepare a surgical plan. This is equivalent to the methodology used by the Navitrack system. The NavioPFS™ uses predefined boundaries generated during the planning process to control the motion of the surgical bur and limit the amount of bone removed in order to shape the condyles and tibial plateau in preparation for placement of the surgical implant. Bur motion is controlled either by retracting the bur in a guard, or by controlling the speed of the bur.</p> | <p>The MAKO RIO uses preoperative CT imaging to create a model of the patient's femur and tibia which allows the surgeon to prepare a surgical plan. The plan is then verified intra-operatively during the procedure. The MAKO RIO uses predefined boundaries generated during the above described planning process to control the motion of the surgical bur and limit the amount of bone removed in order to shape the condyles and tibial plateau in preparation for placement of the surgical implant. The motion is controlled by a robotic arm which provides resistance to movement as the target boundary is approached.</p> | <p>The Navitrack System - OS Unicondylar Knee Universal device consists of software, a computer workstation, an optical tracking system, surgical instruments, and tracking accessories, designed to assist the surgeon in the placement of unicondylar knee replacement components.</p> <p>Tracking devices are incorporated with given surgical instruments, as well as on fixation bases that attach to each of the femur and tibia, such to allow the ability to track and display to the user their respective positions intra-operatively. The femur and tibia are displayed to the user in the form of their main alignment axes. The alignment axes are determined and recorded intra-operatively by identifying the key anatomical references that are used clinically to align and position the components. The Navitrack system does not require a preoperative CT scan.</p> |

| Summary of Similarities and Differences NavioPFS™, MAKO RIO and Navitrack System – OS Unicondylar Knee Universal | | | |
|--|---|--|--|
| <u>Devices</u> | Blue Belt Technologies <i>NavioPFS™</i> | Predicate A. <i>MAKO Surgical Tactile Guidance System v2.0 ("MAKO RIO") (K081867)</i> | Predicate B. <i>The Zimmer (Orthosoft) Navitrack® System - OS Unicondylar Knee Universal (K071714)</i> |
| <u>Construction</u> | Consists of an IR image system (Northern Digital Polaris), reflective trackers, computer, user interface display, various probes, a surgical bur, sterile bur guards, bone screws and clamps. | Consists of an IR image system (Northern Digital Polaris), reflective trackers, computer, user interface display, various probes, a surgical bur bone screws and clamps. | Consists of an IR image system (Northern Digital Polaris), reflective trackers, computer, user interface display, various probes, bone screws and clamps. |
| <u>Pre-Surgical Planning Method</u> | Uses data collected intra-operatively by surgeon during the initial surgical procedure to generate a real time plan of cut surfaces. | Uses DICOM data imported from pre-operative CT scans. | Uses data collected intra-operatively by surgeon during initial surgical procedure to generate real time plan of cut surfaces. Does not require a pre-operative CT scan. |
| <u>Imaging Requirements</u> | None preoperative. Possible post-operative to verify implant placement after surgeon finalizes placement | CT Scans required preoperatively. Possible post-operative scans to confirm implant placement after surgeon finalizes placement. | None preoperative. Possible post-operative to verify implant placement after surgeon finalizes placement |

Nonclinical testing:

Design verification tests were performed on the Blue Belt Technologies NavioPFS™ as a result of the risk analysis and product requirements. Testing included software code reviews, software unit testing, software integration testing, bench verification testing, biocompatibility testing, environmental testing, user manual/labeling inspection, drawing inspections, and a clinical simulation (usability testing). Simulated use testing included testing in simulated knees (sawbones) and cadaver lab testing. Users included surgeons, physician’s assistants, and technical support personnel who were able to successfully use the NavioPFS™ system, and place implants per Blue Belt Technologies’ specifications after being adequately trained.

In addition to the bench and simulated use testing cited above, compliance testing to the following standards was completed.

- IEC 60601-1:2005 Medical Electrical Equipment – Part 1: General Requirements for Safety
- IEC 60601-1-2 Edition 3:2007-03, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests.
- AAMI/ANSI/ISO 11607-1:2006 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2006 Packaging for terminally sterilized medical devices - Part 2: Validation

requirements for forming, sealing and assembly processes

- ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management system
- ANSI/AAMI/ISO 11137-2:2006 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

Discussion of similarities and differences

The NavioPFS™ System uses a combination of two established technologies to prepare bone for attachment of implant components. The NavioPFS™ uses intraoperative data collection (image free or non-CT data generation) to create a model of the patient's femur and tibia and allows the surgeon to prepare a surgical plan. This is equivalent to the methodology used by the Navitrack system.

The NavioPFS™ uses predefined boundaries generated during the planning process to control the motion of the surgical bur and limit the amount of bone removed in order to shape the condyles and tibial plateau in preparation for placement of the surgical implant. This is similar to the methods used by the Mako TGS (RIO) system, although the Mako TGS (RIO) system uses a preoperative CT scan in addition to intra-operatively acquired data to plan the position of implant components.

Clinical testing

No human clinical tests were conducted to determine safety and effectiveness of the NavioPFS™ System.

Summary and Conclusions

In summary, based on the results of the clinical and non-clinical testing, the NavioPFS™ is as safe and effective and performs as well as to the *MAKO Surgical Robotic Arm Interactive Orthopedic System ("MAKO RIO") (K081867)* and *The Zimmer (ORTHOsoft) Navitrack® System - OS Unicodylar Knee Universal (K071714)*.

{End of tab}



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

Blue Belt Technologies, Incorporated
% Mr. Richard G. Confer
Vice President, Regulatory Affairs and Quality Assurance
2828 Liberty Avenue, Suite 100
Pittsburgh, Pennsylvania 15222

November 30, 2012

Re: K121936

Trade/Device Name: NavioPFS™
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 28, 2012
Received: November 01, 2012

Dear Mr. Confer:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TAB 5

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K121936
Device Name: NavioPFS™

Indications for Use:

The NavioPFS™ System is intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

The NavioPFS™ System is indicated for use in surgical knee procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be determined. These procedures include unicondylar knee replacement.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Dwight Yen

2012.11.30 11:09:16 -05'00'

(Division Sign-off)

Division of Surgical Devices

510(k) Number K121936