TAB 005

510(K) SUMMARY

510(k) Owner	Blue Belt Technologies, Inc. 2828 Liberty Ave., Suite 100 Pittsburgh, PA 15222 Tel: (412) 683-3844 Fax: (412) 683-6447
Contact Person	Richard G. Confer Vice President of Quality Assurance and Regulatory Affairs Tel: (412) 683-3844 x 4106 Email: rconfer@bluebelttech.com
Date of Submission	June 27, 2014
Classification Reference	21 CFR 882.4560
Product Code	OLO
Product Codes of Implants Supported by the Navio	HSX, HRY, KRR
Common/Usual Name	Orthopedic Sterotaxic Instrument
Trade/Proprietary Name	Navio™
Predicate Device(s)	Blue Belt Technologies, Inc. *NavioPFS™* (K121936) MAKO Surgical Corp. *Tactile Guidance System v2.0* (K081867)
Reason for Submission	Expanded Indications

Intended Use

The Navio 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 Navio 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 and patellofemoral arthroplasty.

The Navio system is indicated for use with cemented implants only.

This intended use statement is the same as the predicate, MAKO TGS (K081867) and expands the intended use statement of the NavioPFS (K121936) to include the patellofemoral knee replacement application.

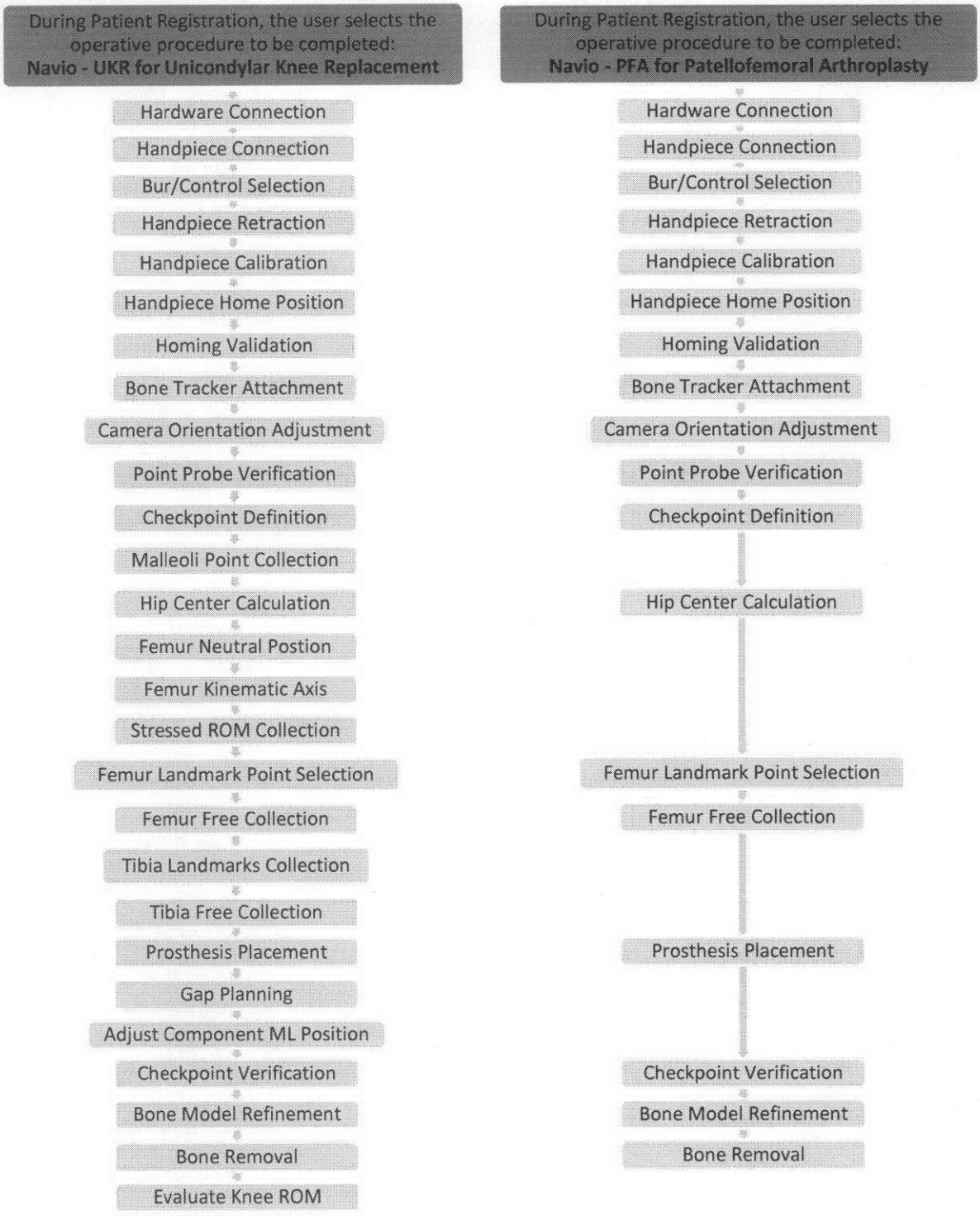
Device Description

The Navio 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 Navio system then aids the surgeon in executing the surgical plan by using a standard off-the-shelf surgical drill motor and bur (eMax 2 Plus System (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 Navio 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 surfaces of the condyle as well as placing post holes.

The Navio 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.

The following diagram shows the primary workflow steps in each application, UKR and PFA. Though the two procedures are very similar, they are mutually independent and cannot be planned or completed in parallel.


During Patient Registration, the user selects the operative procedure to be completed:
Navio - UKR for Unicondylar Knee Replacement
Hardware Connection
Handpiece Connection
Bur/Control Selection
Handpiece Retraction
Handpiece Calibration
Handpiece Home Position
Homing Validation
Bone Tracker Attachment
Camera Orientation Adjustment
Point Probe Verification
Checkpoint Definition
Malleoli Point Collection
Hip Center Calculation
Femur Neutral Postion
Femur Kinematic Axis
Stressed ROM Collection
Femur Landmark Point Selection
Femur Free Collection
Tibia Landmarks Collection
Tibia Free Collection
Prosthesis Placement
Gap Planning
Adjust Component ML Position
Checkpoint Verification
Bone Model Refinement
Bone Removal
Evaluate Knee ROM
During Patient Registration, the user selects the operative procedure to be completed:
Navio - PFA for Patellofemoral Arthroplasty
Hardware Connection
Handpiece Connection
Bur/Control Selection
Handpiece Retraction
Handpiece Calibration
Handpiece Home Position
Homing Validation
Bone Tracker Attachment
Camera Orientation Adjustment
Point Probe Verification
Checkpoint Definition
Hip Center Calculation
Femur Landmark Point Selection
Femur Free Collection
Prosthesis Placement
Checkpoint Verification
Bone Model Refinement
Bone Removal

Summary of Technological Similarities with Predicates:

Summary of Similarities and Differences **Navio, NavioPFS™, and Tactile Guidance System v2.0**			
Devices	**Premarket Notification Subject Device** Blue Belt Technologies *Navio™*	**Predicate A** Blue Belt Technologies *NavioPFS™* (K121936)	**Predicate B** MAKO Surgical Corp. *Tactile Guidance System v2.0 (K081867)*
Technological Characteristics	The Navio system uses established technologies, as described for the NavioPFS, to prepare bone for attachment of implant components. Navio uses intraoperative data collection (image free or non-CT data generation) to create a model of the patient's femur and/or tibia, dependent on the procedure being performed, and allows the surgeon to prepare a surgical plan. This is equivalent to the methodology used by the NavioPFS. The Navio 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, tibial plateau, or patellofemoral joint in preparation for placement of the surgical implant. Bur cutting is controlled either by retracting the bur in a guard, or by controlling the speed of the bur as the target surface is approached.	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. 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 cutting is controlled either by retracting the bur in a guard, or by controlling the speed of the bur as the target surface is approached.	The MAKO TGS 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 TGS 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.
Construction	Consists of an IR image system (Northern Digital Polaris), reflective trackers, computer, user interface display, various probes, a surgical bur, reusable 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, 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.

Summary of Similarities and Differences **Navio, NavioPFS™, and Tactile Guidance System v2.0**			
Devices	**Premarket Notification Subject Device** Blue Belt Technologies *Navio™*	**Predicate A** Blue Belt Technologies *NavioPFS™* (K121936)	**Predicate B** MAKO Surgical Corp. *Tactile Guidance System v2.0 (K081867)*
Pre-Surgical Planning Method	Uses data collected intra-operatively by surgeon during the initial surgical procedure to generate a real time plan of cut surfaces.	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.
Imaging Requirements	None preoperative. Possible post-operative to verify implant placement after surgeon finalizes placement	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.

Nonclinical testing:

Design verification tests were performed on the Blue Belt Technologies Navio system as a result of the risk analysis and product requirements. Testing included software code reviews, software unit testing, software integration testing, bench verification 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 Navio system and place implants per Blue Belt Technologies' specifications after being adequately trained.

Discussion of similarities and differences

The Navio system uses established technologies to prepare bone for attachment of implant components. Navio 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. The Navio 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, tibial plateau, or patellofemoral joint in preparation for placement of the surgical implant. This is equivalent to the methodology used by the NavioPFS™ system except for the Navio's additional capability to prepare the patellofemoral joint for implant.

The Navio 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, tibial plateau, and/or the patellofemoral joint in preparation for placement of the surgical implant. This is similar to the methods used by the MAKO TGS system to prepare the condyles, tibial plateau, and patellofemoral joint, although the MAKO TGS system uses a preoperative CT scan in addition to intra-operatively acquired data to plan the position of implant components.

Though the UKR and PFA procedures are very similar, they are mutually independent and cannot be planned or completed in parallel. If the user is completing a bi-compartmental knee joint replacement in which a patellofemoral arthroplasty and a unicondylar knee replacement are both being performed, preparation of the patellofemoral joint must be completed independently of the preparations of the femoral condyle and tibial plateau surfaces.

Clinical testing

No human clinical tests were conducted to determine safety and effectiveness of the Navio system.

Summary and Conclusions

The Navio system has the same intended use as the MAKO TGS system (K081867) and has the same technological characteristics as the NavioPFS system (K121936). Non clinical testing was completed to verify that the differences in technological characteristics and workflow do not raise any new issues of safety or effectiveness. The information presented in this 510(k) notification demonstrates that the Navio is as safe and effective and performs as well as the *Blue Belt Technologies NavioPFS™* (K121936) or the *MAKO Surgical Corp. Tactile Guidance System v2.0 (K081867).*

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

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

July 2, 2014

Re: K140596
Trade/Device Name: Navio
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO, HSX, HRY, KRR
Dated: June 5, 2014
Received: June 6, 2014

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
unknown K140596

Device Name
Navio

Indications for Use *(Describe)*
The Navio 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 Navio 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 and patellofemoral arthroplasty.

The Navio system is indicated for use with cemented implants only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices