DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 19, 2016

Blue Belt Technologies, Incorporation
Mr. Richard Confer
Vice President of Regulatory Affairs
2905 Northwest Boulevard, Suite 40
Plymouth, Minnesota 55441

Re: K160537
Trade/Device Name: Navio®
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO, HSX, HRY, KRR, NPJ, JWH
Dated: February 24, 2016
Received: February 26, 2016

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 Parts 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 below.

510(k) Number *(if known)*
XXXXXXX K160537

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 (UKR), patellofemoral arthroplasty (PFA), and total knee arthroplasty (TKA).

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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BLUE BELT TECHNOLOGIES

2905 Northwest Boulevard, Suite 40, Plymouth, Minnesota 55441 USA
Tel 763.452.4950 Fax 763.452.4675 www.bluebelttech.com

510(k) Summary

510(k) Owner	Blue Belt Technologies, Inc. 2905 Northwest Blvd Ste. 40 Plymouth, MN 55441 USA Tel: (763) 452-4950 Fax: (763) 452-4675
Contact Person	Richard G. Confer Vice President of Regulatory Affairs Tel: (412) 683-3844 x 4106 Email: Rick.Confer@smith-nephew.com
Date of Submission	February 24, 2016
Classification Reference	21 CFR 882.4560
Product Code	OLO
Supported Codes	HSX, HRY, KRR, NPJ, JWH
Common/Usual Name	Orthopedic Sterotaxic Instrument
Trade/Proprietary Name	Navio®
Predicate Device(s)	Navio® (K152574)
Reason for Submission	Expanded indications for use to include total knee arthroplasty (TKA), which adds JWH as a supported product code.

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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.

Indications for Use

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 (UKR), patellofemoral arthroplasty (PFA), and total knee arthroplasty (TKA).

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

The Intended Use Statement is consistent with that of Navio®, the predicate device, cleared via K121936, K140596, K143668, and K152574. This expanded Indications for Use Statement includes the addition of total knee arthroplasty and support for product code JWH, per regulation number 888.3560.

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 both establishing a bone surface model for the target surgery and in planning the surgical implant location, based on intraoperatively-defined bone landmarks and known geometry 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 (Anspach eMax2 Plus System, cleared via K080802), which has been adapted using a tracking system.

The surgical bur is inserted into a handpiece, which allows the bur to move within the handpiece. The Navio system 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. This is referred to as Exposure Control mode.

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 target 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 and fixation features.

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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 each data line entry, patient and procedure ID, implant ID, step in process, and error messages received by the user during the procedure. This data can be archived to a CD upon demand at the end of the procedure and is anonymized.

The following diagram shows the primary workflow steps in each application: UKR, PFA, and TKA. The three procedures are mutually independent and cannot be planned or completed in parallel.

Note: The workflow for UKR and PFA procedures has not changed from the predicate device, cleared via K152574.

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Figure 007-1a. Comparison of Workflows *(Part 1 of 2)*

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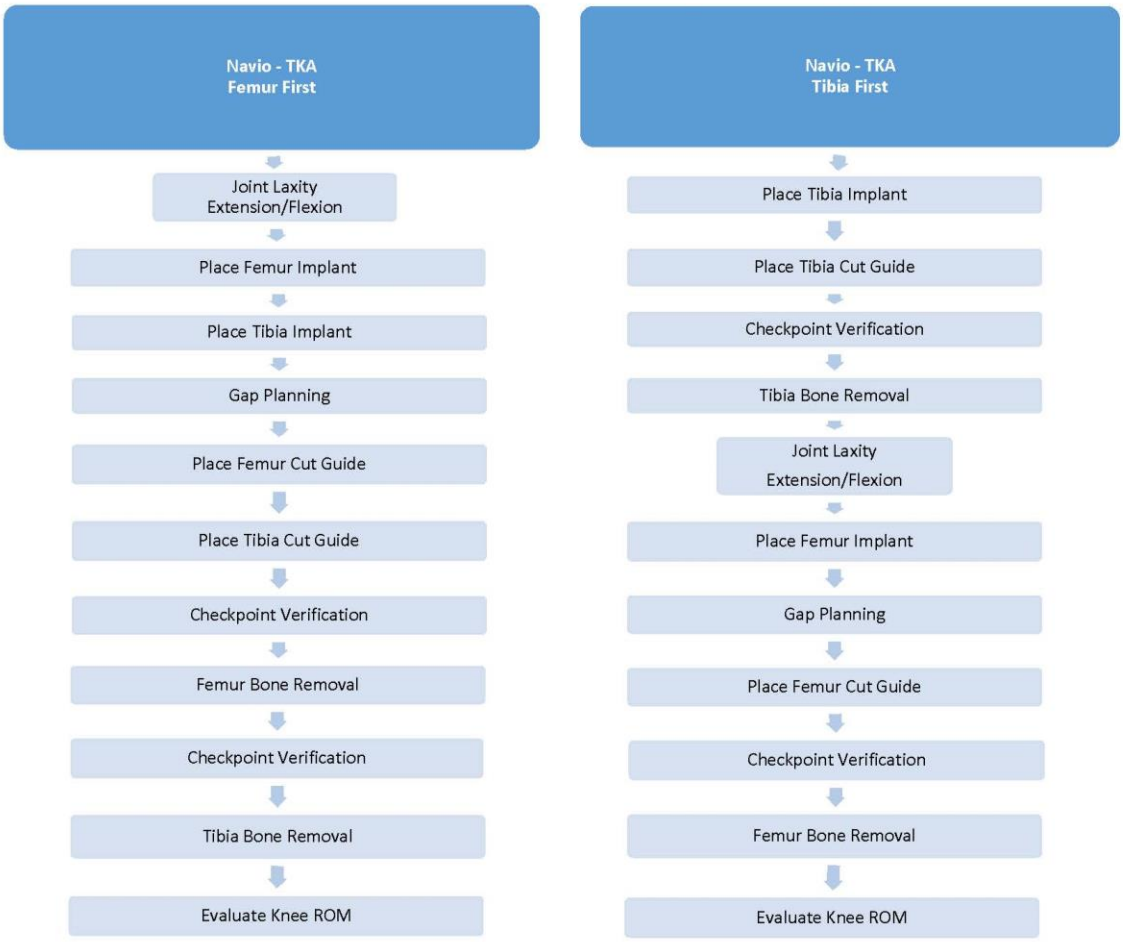
Figure 007-1b. Comparison of Workflows *(Part 2 of 2)*



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Currently supported implants include:

Implant Model Name	Manufacturer	510(k) number
NEO Total Knee System	New Era Orthopedics	K142388
Journey II CR	Smith and Nephew	K121443

Table 007-1. Summary of Technological Similarities with Predicate

Devices	**Subject Device** **Navio with Total Knee Arthroplasty Application**	**Predicate Device** **Navio [K152574]**
Intended use	Same as Predicate	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.
Indications for Use	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, patellofemoral arthroplasty, and total knee arthroplasty. The Navio system is indicated for use with cemented implants only.	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.
Supported Product Code(s)	HSX, HRY, KRR, NPJ, JWH	HSX, HRY, KRR, NPJ

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Devices	Subject Device Navio with Total Knee Arthroplasty Application	Predicate Device Navio [K152574]
Environment of Use	Same as Predicate	Intended for use by trained orthopedic surgeons in an orthopedic surgical suite.
Technological Characteristics	The Navio system uses established technologies to prepare bone for attachment of implant components, or in the case of a total knee arthroplasty, the bone surface is prepared to receive the femoral and tibial cutting guides. 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. The Navio system uses pre-defined 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, or in the case of a total knee arthroplasty, the bone surface is prepared to receive the femoral and tibial cutting guides. Bone surface for receiving the implant is	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/or tibia, dependent on the procedure being performed, and allows the surgeon to prepare a surgical plan. The Navio system uses pre-defined 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.

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Devices	Subject Device Navio with Total Knee Arthroplasty Application	Predicate Device Navio [K152574]
	prepared using a standard surgical saw. 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.	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.

Non-Clinical Testing (Bench)

Design verification tests were performed on the Blue Belt Technologies, Inc. Navio system to support total knee arthroplasty, as a result of the risk analysis and product requirements. Testing included software database reviews, bench testing, labeling inspection, drawing inspections, and a clinical simulation (usability testing). Simulated-use testing included simulated knee (sawbones) and cadaver laboratory testing. Users included surgeons, physician's assistants, and technical support personnel who were able to successfully use the Navio system to place total knee implant systems per Blue Belt Technologies' and implant manufacturer's specifications after being adequately trained.

Clinical Testing

No human clinical testing was conducted to determine safety and effectiveness of the Navio system.

Discussion of Similarities and Differences

The predicate, Navio, uses established technologies to prepare bone for attachment of implant components. The predicate uses intraoperative data collection (image-free or non-CT data generation) to create a model of the patient's femur and/or tibia and allow the surgeon to prepare a surgical plan. The predicate uses pre-defined 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 methodology is equivalent to what is used by the Navio, the subject of this 510(k), with the exception of the Navio's expanded indication to prepare the knee for a total

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knee arthroplasty. During a total knee arthroplasty procedure, the Navio controls the cutting action of the bur during the placement of the cutting guides. The surgeon then uses the Navio-placed cutting guides to finish the preparation of the bone surface using standard surgical saws and the manual instrumentation technique established by each implant's manufacturer to prepare the remainder of the bone surface to receive the total knee implant components.

The Navio surgical system uses pre-defined 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, or in the case of a total knee arthroplasty, the bone surface is prepared to receive the femoral and tibial cutting guides. This submission supports the expanded indication for use of the Navio system to place total knee implants using the same techniques used in the predicate Navio system.

The UKR, PFA, and TKA applications are mutually independent and cannot be planned or completed in parallel.

Conclusions

The Navio system described in this submission has the same intended use and the same technological characteristics as the Navio system, cleared per K121936, K140596, K143668, and K152574, with the additional indication of total knee arthroplasty. Non-clinical testing was completed to verify that the use of the Navio system to assist with placement of total knee implants does not raise any new issues of safety or effectiveness. The information presented in this 510(k) premarket notification demonstrates that the Navio, when used to place total knee implants, is as safe and effective as the currently cleared Navio system.