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 2, 2017

Blue Belt Technologies, Inc.
Richard Confer
Director, Regulatory Affairs
2905 Northwest Blvd.
Ste. 40
Plymouth, Minnesota 55441

Re: K170360
Trade/Device Name: Navio
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, HRY, KRR, NPJ, JWH, HSX
Dated: February 2, 2017
Received: February 6, 2017

Dear Richard 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" (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 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,

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)*
[redacted] K170360

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

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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 Director, Regulatory Affairs Tel: (412) 683-3844 x 4106 Email: rick.confer@smith-nephew.com
Date of Submission	February 2, 2017
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◇ Surgical System (NAVIO system)
Predicate Device(s)	NAVIO system (K160537)
Reason for Submission	Addition of the Smith & Nephew LEGION◇ Total Knee System CR/PS and GENESIS◇ II CR/PS Total Knee System to the list of supported implants, updates to the NAVIO Total Knee Arthroplasty (TKA) instrument kit and components, and feature enhancements to the NAVIO system TKA software.

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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 and Indications for Use statements are the same as the predicate device.

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 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 cutting engagement of the surgical bur based on its proximity to the planned target surface. The cutting control is achieved in two ways:

- **Exposure control** adjusts the bur's exposure with respect to a guard. If the surgeon encroaches on a portion of bone that is not to be cut, the NAVIO system retracts the bur inside the guard, disabling cutting.
- **Speed control** regulates the signal going to the drill motor controller itself and will limit the speed of the drill if the target surface is approached. This mode of operation is useful in shaping surfaces of the condyle as well as placing post holes and fixation features for femoral and tibial cut guides.

Additionally, the surgeon can disable both controls and operate the NAVIO system handpiece as a standard navigated surgical drill. The surgeon must press on a footpedal to activate the surgical bur and enable cutting in all modes.

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UKR and PFA Overview

In the UKR and PFA applications, the NAVIO system uses established technologies to prepare bone for attachment of implant components. The NAVIO system uses intraoperative data collection (image-free or non-CT data generation) to create a model of the patient's femur and/or tibia, depending 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.

TKA Overview

Similar to the UKR and PFA applications, the TKA application uses intraoperative data collection to create a model of the patient's femur and tibia and allows the surgeon to prepare a surgical plan. In the TKA application, the NAVIO system is used to plan the location of the femur and tibia implants, as well as cut guides and position the features used to secure the cut guides in place. The NAVIO system controls the cutting action of the bur during placement of the femur and tibia cut guides. The surgeon finishes the preparation of the bone surface using standard surgical saws, guided by the slots in the cut guides. Cutting action of the saw is not controlled by the NAVIO system. The surgeon follows the implant manufacturer's recommended procedure to remove bone and place the implant, just as if the cut guide had been placed manually. The manual instrumentation technique established by each implant's manufacturer is used to prepare the remainder of the bone surface to receive the total knee implant components.

One of the enhancements to the TKA application software is the addition of a Bur All feature that enables the surgeon to prepare bone for the attachment of total knee implant components. Using the same method of bone removal as the UKR and PFA applications, the NAVIO system controls the bur either by retracting the bur in a guard (Exposure Control) or by controlling the speed of the bur (Speed Control) as the target surface is approached. The Bur All feature also provides a way for a surgeon that performed bulk bone removal using a standard surgical saw to refine the bone model and make additional fine cuts to clean up the bone surface to receive the implant.

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 workflows for UKR and PFA procedures have not changed from the predicate device, cleared via K160537.

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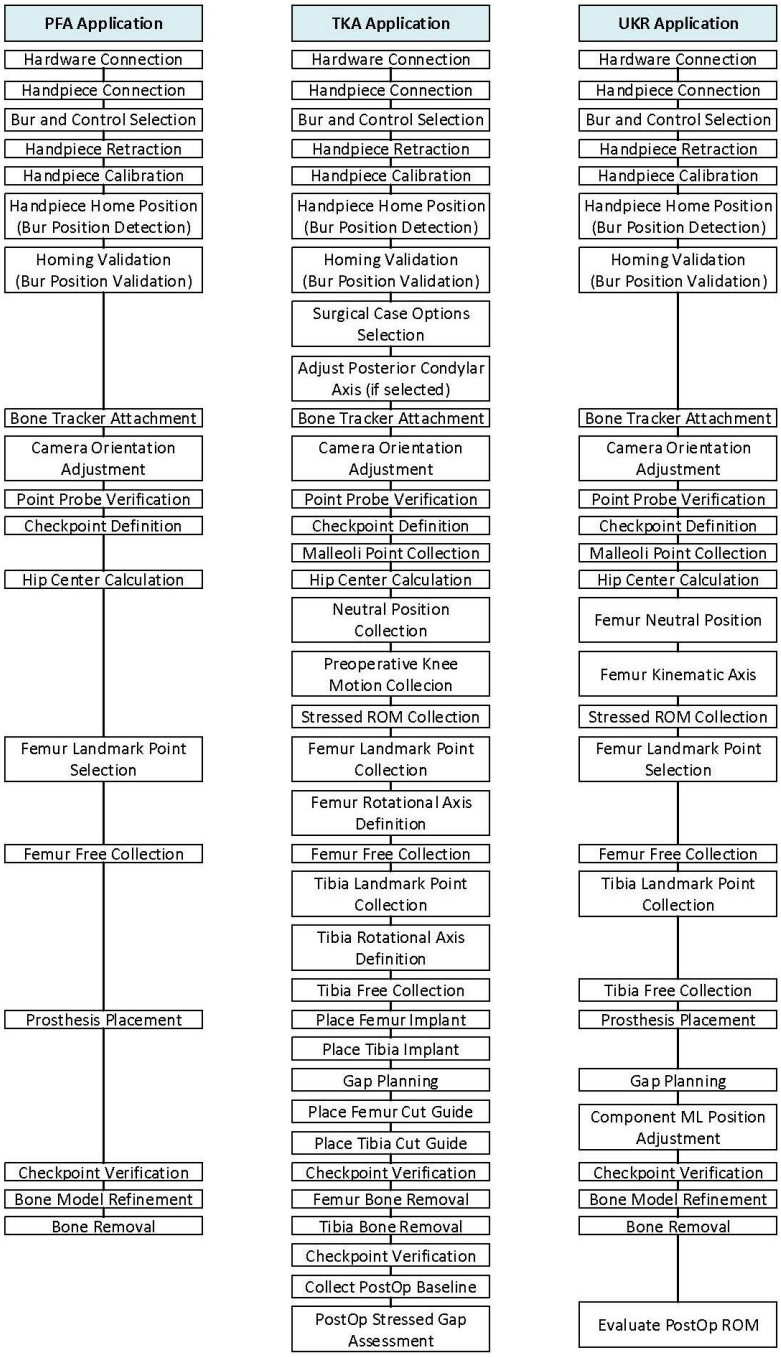
Figure 1: NAVIO System Workflows - UKR, PFA, and TKA



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Currently Supported Total Knee Implants

Implant Model Name	Manufacturer	510(k) Number
JOURNEY II CR	Smith and Nephew	K121443
JOURNEY II BCS	Smith and Nephew	K111711
GENESIS II CR/PS	Smith and Nephew	K951987, K962557
LEGION CR/PS	Smith and Nephew	K951987, K962557, K093746
NEO Total Knee System	New Era Orthopedics	K142388

Discussion of Similarities and Differences

The NAVIO system presented in this 510(k) submission is substantially equivalent to the predicate NAVIO, K160537. The intended use, indications for use, and the general functionality of the NAVIO system are unchanged from the previously submitted device.

This submission supports the following updates to the NAVIO system:

- the addition of the Smith & Nephew LEGION Total Knee System CR/PS and GENESIS II Total Knee System CR/PS to the list of supported implants,
- updates to the NAVIO TKA instrument kit and components, and
- feature enhancements to the NAVIO system Total Knee Application software.

The implant product codes supported by the subject device are consistent with the predicate device. The LEGION Total Knee System CR/PS and GENESIS II Total Knee System are cemented implants that share the product code JWH, a currently supported NAVIO product code. These implants have been successfully imported and appropriately validated for use with the NAVIO system.

The NAVIO TKA instrument kit was updated to include two new components: a new femur drill guide to support the LEGION-GENESIS II CR/PS implants and a new Twin Peg Tibia Cut Guide.

Feature enhancements were made to the NAVIO TKA application software. The NAVIO system TKA workflow, described in K160537, has been updated to improve usability of the application, simplify the user interface to remove features that were not being utilized, and to introduce new features. One of the primary features that is being introduced is the option to use the NAVIO handpiece to bur away all bone necessary to accurately place a total knee implant component; this functionality is similar to the UKR and PFA applications.

The established technologies that are used by the NAVIO system to prepare bone for attachment of implant components or for the attachment of the TKA femur and tibia cutting guides are unchanged.

Figure 2: Summary of Technological Similarities with Predicate

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	Subject Device NAVIO [Subject]	Predicate Device NAVIO [K160537]
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	Same as Predicate.	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.
Supported Product Code(s)	Same as Predicate.	HSX, HRY, KRR, NPJ, JWH
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 UKR, PFA, or TKA implant components. In the case of a total knee arthroplasty, the bone surface may also be 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	The NAVIO system uses established technologies to prepare bone for attachment of UKR and PFA 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

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	performed, and allows the surgeon to prepare a surgical plan. The NAVIO system 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. During a TKA procedure, the surgeon may choose to prepare the bone surface for receiving the implant by utilizing the Bur All method or the bone surface may be prepared to receive the femoral and tibial cutting guides (if cut guides are utilized, the bone surface is 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.	performed, and allows the surgeon to prepare a surgical plan. The NAVIO system 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, or in the case of a total knee replacement procedure, the bone surface is prepared to receive the femoral and tibial cutting guides. Bone surface for receiving the implant is 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.

Non-Clinical Testing (Bench)

Design verification and validation tests were performed on the NAVIO system to support the updates presented in this submission. Testing included software database reviews, bench testing, labeling inspection, drawing inspections, and usability testing.

Trained surgeons and technical support personnel performed verification accuracy testing using simulated knees (sawbones) and cadaver laboratory testing. Usability testing validated that surgeon users were able to perform a TKA procedure on cadaver in a simulated operating room environment safely and effectively using the NAVIO system with TKA application.

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Clinical Testing

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

Conclusions

The NAVIO system described in this submission has the same intended use and the same technological characteristics as the NAVIO system, most recently cleared per K160537. The differences in the methodology of bone removal between the previously cleared NAVIO system (K160537) and the additional supported total knee implant systems, as well as updated instrumentation, and software feature enhancements, do not raise any new questions of safety or effectiveness.

The key determining factor is whether NAVIO control can be applied accurately to accomplish the desired cutting in accordance with the plan without exceeding the predefined limits. The accuracy verification testing performed indicates that the total knee implant placement accuracy using Bur All method of bone removal is acceptable and similar to the implant placement accuracy required for unicondylar and patellofemoral implant placement. Additionally, placement of the LEGION CR/PS and GENESIS II CR/PS Total Knee Implant systems using the NAVIO TKA cut guides (including the new Tibia Twin Peg cut guides) is acceptable and similar to the placement accuracy presented in the previous 510(k). Usability validation testing demonstrated that surgeon users were able to perform a TKA procedure on cadaver in a simulated operating room environment safely and effectively using the NAVIO system with TKA application.

The NAVIO system presented in this 510(k) premarket notification demonstrates that the updated NAVIO system, with these additional supported total knee implants, instrument tray and component changes, and software feature enhancements, continues to be as safe and effective as the predicate NAVIO system (K121936, K140596, K143668, K152574, and K160537).

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