June 28, 2019

Blue Belt Technologies, Inc.
Amy Winegarden
Regulatory Affairs Specialist II
2905 Northwest Blvd., Ste. 40
Plymouth, Minnesota 55441

Re: K191223
Trade/Device Name: Navio Surgical System (NAVIO system)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 23, 2019
Received: May 28, 2019

Dear Amy Winegarden:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For- Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Stereotaxic, Trauma
and Restorative Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191223

Device Name
NAVIO™ Surgical System (NAVIO system)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Submitted by:	Blue Belt Technologies, Inc. 2905 Northwest Blvd Ste. 40 Plymouth, MN 55441 USA Tel: (763) 452-4950 Fax: (763) 452-4675
Date of Submission:	June 27, 2019
Contact Person:	Amy Winegarden Regulatory Affairs Specialist II T (412) 683-3844 x4135 Email: Amy.Winegarden@smith-nephew.com
Name of Device:	NAVIO◇ Surgical System (NAVIO system)
Common Name:	Orthopedic Stereotaxic Instrument
Device Classification Name and Reference:	21 CFR 882.4560
Device Class:	Class II
Product Code:	OLO
Supported Codes:	HSX, HRY, KRR, NPJ, JWH
Predicate Device:	NAVIO™ Surgical System (K180271)

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.

Currently Supported Total Knee Implants

The following total knee implants are supported on the Navio system:

Table 1: 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
JOURNEY II XR	Smith and Nephew	K141471, K152726
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, K180271. 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 modifications to the NAVIO system:

1. Updates to the NAVIO TKA instrument kit, including the addition of NAVIO system distal femur punches.
2. Updates to the NAVIO system labeling.
3. Qualification of a new implant database for the Smith & Nephew ANTHEM Total Knee System (K142807).
4. Workflow, user interface, and infrastructure updates to the NAVIO system Total Knee Application (TKA) software.

The implant product codes supported by the subject device are consistent with the predicate device. 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. The UKR and PFA workflows have not changed from the predicate device, cleared via K180271.

Table: Predicate Devices Manufacturer	**Description**	**Submission Number**	**Clearance Date**
Blue Belt Technologies, Inc.	NAVIO Surgical System	K180271	2/12/2018

Non-Clinical Testing (Bench)

Design verification and validation tests were performed on the NAVIO surgical system to support the changes presented in this submission. Testing included software code reviews, bench testing, summative usability testing, and labeling verification and validation testing.

Trained technical support personnel performed verification and validation testing to ensure that the changes made to the NAVIO system, including the updates to the NAVIO TKA instrument kit, addition of distal femur punches, updated labeling, qualification of a new implant database, and software modifications, performed as intended and that the subject device is as safe and effective as the predicate device.

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 K180271. The updates to the instrument kit, addition of distal femur punches, updated labeling, qualification of a new implant database, and software modifications 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. The verification testing performed demonstrates that the updated NAVIO system meets the same accuracy specifications required for the predicate device.

The NAVIO system presented in this 510(k) premarket notification demonstrates that the updated NAVIO system continues to be as safe and effective as the predicate NAVIO system (K180271).