June 12, 2020

Blue Belt Technologies, Inc.
Corrine Herlinger
Principal Regulatory Affairs Specialist
2905 Northwest Blvd., Ste. 40
Plymouth, Minnesota 55441

Re: K201022
Trade/Device Name: Real Intelligence Cori
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, HSX, HRY, NPJ
Dated: May 14, 2020
Received: May 15, 2020

Dear Corrine Herlinger:

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,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*
K201022

Device Name
REAL INTELLIGENCE CORI (CORI)

Indications for Use *(Describe)*
CORI 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) and total knee arthroplasty (TKA).

CORI 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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	Corrine Herlinger Principal Regulatory Affairs Specialist Tel: 412-683-3844 x4128 Email: corrine.herlinger@smith-nephew.com
Date Prepared	June 12, 2020
Classification Reference	21 CFR 882.4560
Product Code	OLO
Supported Codes	HSX, HRY, NPJ
Common/Usual Name	Orthopedic Stereotaxic Instrument
Trade/Proprietary Name	REAL INTELLIGENCE◇ CORI◇ (CORI)
Predicate Device(s)	REAL INTELLIGENCE◇ CORI◇ (CORI) (K193120) (Primary Predicate) NAVIO Surgical System (Navio system) (K191223)
Reason for Submission	New Indication

BLUE BELT TECHNOLOGIES

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

Intended Use

REAL INTELLIGENCE CORI (CORI) 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

CORI 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) and total knee arthroplasty (TKA).

CORI is indicated for use with cemented implants only.

Device Description

CORI is a computer-assisted orthopedic surgical navigation and surgical burring system. CORI 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, CORI aids the surgeon in establishing a bone surface model for the target surgery and planning the surgical implant location.

CORI software controls the cutting engagement of the surgical bur based on its proximity to the planned target surface. The cutting control is achieved with two modes:

- **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 robotic system retracts the bur inside the guard, disabling cutting.
- **Speed control** regulates the signal going to the drill motor controller itself and limits the speed of the drill if the target surface is approached.

Alternatively, the surgeon can disable both controls and operate the robotic drill as a standard navigated surgical drill.

Currently Supported Knee Implants

The following knee implants are supported on CORI:

Table 1: Currently Supported Knee Implants

Implant Model Name	Manufacturer	510(k) Number
JOURNEY II Unicompartmental Knee System	Smith and Nephew	K191211
JOURNEY UNI	Smith and Nephew	K102069
STRIDE Unicondylar Knee	Smith and Nephew	K123380
ZUK Select Knee System	Smith and Nephew	K160738
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
ANTHEM	Smith and Nephew	K142807

Discussion of Similarities and Differences

The subject device, CORI, is substantially equivalent to the predicate devices: CORI (K193120) and the Navio system (K191223). The intended use and the established technologies used to prepare bone for the attachment of implant components, including implant accuracy, is the same as the predicate devices. The CORI UKR and TKA software applications feature a workflow that is nearly identical to the predicate devices, cleared via K191223 and K193120.

Table 2: Summary of Technological Similarities with Predicates

Devices	Subject Device CORI	Primary Predicate CORI [K193120]	Secondary Predicate NAVIO Surgical System [K191223]
Intended Use	REAL INTELLIGENCE CORI (CORI) is intended to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.	REAL INTELLIGENCE CORI (CORI) 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 Surgical System is intended to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

Devices	Subject Device CORI	Primary Predicate CORI [K193120]	Secondary Predicate NAVIO Surgical System [K191223]
Indications for Use	CORI 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 total knee arthroplasty. CORI is indicated for use with cemented implants only.	CORI is indicated for use in unicondylar knee replacement (UKR) surgical knee procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be determined. CORI 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, patellofemoral arthroplasty, and total knee arthroplasty. The NAVIO system is indicated for use with cemented implants only.
Implant Product Codes Supported	HSX, HRY, NPJ		HRY, HSX, JWH, KRR, NPJ
Environment of Use	Same as primary predicate.	CORI is intended to be used by trained medical professionals in a hospital or clinical setting equivalent to an orthopedic surgery suite.	
Technological Characteristics	CORI uses established technologies to prepare bone for attachment of UKR and 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. CORI uses intraoperative data collection (image-free or non-CT data generation) to create a model of the		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

Devices	Subject Device CORI	Primary Predicate CORI [K193120]	Secondary Predicate NAVIO Surgical System [K191223]
	patient's femur and/or tibia, dependent on the procedure being performed, and allows the surgeon to prepare a surgical plan. CORI 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 or tibial plateau 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 using the Bur All method or the bone surface is prepared to receive the femoral and tibial cutting guides with final bone surface for receiving the implant 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.		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 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 using the Bur All method or the bone surface is prepared to receive the femoral and tibial cutting guides with final bone surface for receiving the implant 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.

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

Non-Clinical Testing (Bench)

Design verification and validation testing was performed to demonstrate that CORI meets all design requirements and is as safe and effective as its predicate devices.

Comprehensive performance testing demonstrated that the system meets required design inputs. Performance data consisted of physical performance test for all system components and system accuracy testing. Additionally, the following testing was conducted:

- **Biocompatibility testing** demonstrating that the system satisfies the requirements of BS EN ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management process.
- **Software verification testing**, including software integration and workflow testing, was completed. Software was developed in accordance with *IEC 62304 Medical device software - Software life cycle processes*, and this submission contains documentation per the requirements of FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.
- **Usability Engineering Validation Testing** demonstrating that representative users were able to safely and effectively use CORI in a simulated use environment.

No human clinical testing was required to determine the safety and effectiveness of CORI.

Conclusions

The subject device, CORI, described in this submission has the same intended use and the same technological characteristics as the predicate devices, CORI (K193120) and the NAVIO system (K191223). The primary difference between the subject device and CORI (K193120) is the update to the system's indications for use to add the TKA application onto the CORI system. The CORI TKA application is based on existing NAVIO TKA software version 7.0. The main functionality of the TKA software is the same as presented in K191223, with modifications to allow for communication with the CORI accessories (robotic drill, tablet, foot pedal, camera, and optional monitor).

The key determining factor in establishing substantial equivalence is whether CORI can accurately accomplish the desired bone cutting in accordance with the surgical plan. The comparative results of the cut-to-plan accuracy data is acceptable and equivalent to the predicate devices. Usability engineering test results demonstrate that representative users are able to use the subject device safely and effectively in a simulated use environment. The information presented in this Special 510(k) premarket notification demonstrates that the updated CORI is as safe and effective as the predicates, CORI (K193120) and the NAVIO system (K191223). Blue Belt Technologies believes that FDA can find CORI to be substantially equivalent to the predicate devices.