November 3, 2021

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

Re: K212537
Trade/Device Name: REAL INTELLIGENCE CORI (CORI)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 10, 2021
Received: August 12, 2021

Dear Sarah Plittman:

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, M.P.H.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212537

Device Name
REAL INTELLIGENCE CORI (CORI)

Indications for Use *(Describe)*
CORI is indicated for use in surgical 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), total knee arthroplasty (TKA) and total hip arthroplasty (THA).

For Knee applications, 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 (K212537)

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	Sarah Plittman Regulatory Affairs Specialist II Tel: 423-838-4454 Email: sarah.plittman@smith-nephew.com
Date of Submission	08/10/2021
Classification Reference	21 CFR 882.4560
Product Code	OLO
Common/Usual Name	Orthopedic Stereotaxic Instrument
Trade/Proprietary Name	REAL INTELLIGENCE◇ CORI◇ (CORI)
Primary Predicate Device	REAL INTELLIGENCE◇ CORI◇ (CORI) (K201022)
Reference Device	Brainlab AG HIP7 (K193307)
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 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), total knee arthroplasty (TKA) and total hip arthroplasty (THA).

For Knee applications, 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.

For robotic knee applications, CORI software can control the cutting engagement of the surgical bur based on its proximity to the planned target surface. Alternatively, the surgeon can disable both controls and operate the robotic drill as a standard navigated surgical drill.

For the hip navigation application, CORI incorporates the Brainlab HIP7 software (K193307) which will be market by Smith & Nephew as RI.HIP NAVIGATION. It uses instruments and reference arrays, which are tracked by the IR camera, to determine pelvis and femur anatomical landmarks as well as implant orientation. RI.HIP NAVIGATION assists the orientation of prosthetic hip implants and enables measurement of leg length and offset when used intra-operatively in combination with CORI.

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

Discussion of Similarities and Differences

The subject device, CORI, is substantially equivalent to the predicate device CORI (K201022).

For knee applications, functionality of the subject device is the same as the predicate device. Functionality has been added to support the THA application.

***Table** 1: Summary of Technological Similarities with Predicate*

Devices	Subject Device REAL INTELLIGENCE CORI [K212537]	Predicate Device REAL INTELLIGENCE CORI [K201022]
Intended use	Same as Predicate.	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 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), total knee arthroplasty (TKA), and total hip arthroplasty (THA). For knee applications, CORI is indicated for use with cemented implants only.	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.
Contraindications	Same as Predicate for UKR and TKA.	CORI is not intended to be used on children, pregnant women, patients who have mental or neuromuscular disorders that do not allow control of the knee joint, morbidly obese patients, or any other patients contraindicated for knee replacement.
Anatomical Site	The subject device is intended for knee and hip joint replacement surgery.	The CORI system is intended for knee joint replacement surgery only.

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

Devices	Subject Device REAL INTELLIGENCE CORI [K212537]	Predicate Device REAL INTELLIGENCE CORI [K201022]
Environment of Use	Same as Predicate.	CORI is intended to be used by trained medical professionals in a hospital or clinical setting equivalent to an orthopedic surgery suite.
Energy Used	Same as Predicate.	Rated Supply Voltage: 100-240 V ~, 50/60 Hz Robotics Console Power Rating: 175VA Robotics Cart Power Rating: 230VA
Compatibility with the Environment and Other Devices	Same as Predicate.	60601-1-2 Edition 4.0 2014-02 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

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

Devices	Subject Device REAL INTELLIGENCE CORI [K212537]	Predicate Device REAL INTELLIGENCE CORI [K201022]
Technological Characteristics	Same as Predicate for UKR and TKA with the following additions: The subject device adds a Virtual Machine with hypervisor to enable the Windows-based HIP7 software to run on CORI. The subject device adds a new USB 2.0 to Ethernet Adapter that will attach to the CORI console. The USB 2.0 to Ethernet Adapter will only interact with the CORI system through the Virtual Machine when using the Hip application.	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 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.

Brainlab HIP7 (K193307) is being listed as a reference device because the subject device is incorporating the HIP7 software and instruments cleared in K193307 to support its new THA indication. The Brainlab HIP7 software and instruments are unchanged from those previously cleared in K193307. There is no change to the HIP7 intended use, indications for use, technological characteristics, or instrumentation as a result of including the HIP7 software on the subject device.

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 tests were performed on CORI to demonstrate that the changes presented in this submission meet all design input requirements and that CORI is as safe and effective as its predicate device. Refer to *Section 11: Summary of Design Control Activities* for the results of the testing performed.

Additionally, the following testing was conducted:

- **Software Integration 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 with the THA application 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 similar technological characteristics as the predicate device, CORI (K201022). The primary difference between the subject device and CORI (K201022) is the addition of the THA indication supported by HIP7 software, the Virtual Machine, and the optional USB 2.0 to Ethernet Connector. The THA application incorporates HIP7 software (reference device K193307) onto CORI via a virtual machine. The indications for use, functionality, and technological characteristics of the HIP7 software are the identical as presented in K193307. The HIP7 software, and the instrumentation necessary to complete a THA navigation procedure, remains unchanged from what was cleared in K193307.

Performance testing of these minor differences has demonstrated that the subject device is substantially equivalent to the predicate device (K201022) and that these differences raise no new questions of safety or effectiveness. The subject device continues to meet design requirements, is as safe and effective as its predicate device, and performs according to its intended use. The information presented in this 510(k) premarket notification demonstrates that the subject device is substantially equivalent and as safe and effective as the predicate, CORI (K201022). Blue Belt Technologies believes that FDA can find the subject device to be substantially equivalent to the predicate device.