August 19, 2022

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

Re: K221224
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: July 21, 2022
Received: July 21, 2022

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,

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)*
K221224

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).

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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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	Corrine Herlinger Principal Regulatory Affairs Specialist Tel: (412) 683-3844 x 4128 Email: corrine.herlinger@smith-nephew.com
Date of Submission	April 26, 2022
Classification Reference	21 CFR 882.4560
Product Code	OLO
Supported Codes	HSX, JWH, MBH
Common/Usual Name	Orthopedic Stereotaxic Instrument
Trade/Proprietary Name	REAL INTELLIGENCE◇ CORI◇ (CORI)
Primary Predicate Device	REAL INTELLIGENCE◇ CORI◇ (K220255)
Secondary Predicate Device	OMNIBotics Knee System (K200888)
Reason for Submission	This Traditional 510(k) submission supports an update to CORI to allow the system to be used with the CORI Knee TENSIONER (TENSIONER) and the associated software upgrade, CORI 1.7.

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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).

Device Description

The subject of this Traditional 510(k) is REAL INTELLIGENCE CORI (CORI), a robotic-assisted orthopedic surgical navigation and burring system. CORI uses established technologies of navigation via a passive infrared tracking camera. Based on intraoperatively-defined bone landmarks and known geometry of the surgical implant, the system aids the surgeon in establishing a bone surface model for the target surgery and planning the surgical implant location. For knee applications, CORI then aids the surgeon in executing the surgical plan by controlling the cutting engagement of the surgical bur.

CORI knee application 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 tool control unit 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 Smith+Nephew knee implants are supported on CORI:

Table 1: Currently Supported Smith+ Nephew Knee Implants

Implant Model Name	510(k) Number	Classification Product Code
STRIDE Unicondylar Knee	K123380	HSX
ZUK Select Knee System	K160738	HSX
JOURNEY II Unicompartmental Knee System	K191211	HSX
JOURNEY UNI	K102069	HSX
JOURNEY II CR	K121443	JWH
JOURNEY II BCS	K111711	JWH
JOURNEY II XR	K141471, K152726	JWH
LEGION CR/PS	K951987, K962557, K093746	JWH
LEGION Porous CR Femoral Components	K073325, K091543	MBH
LEGION Porous CR Narrow Femoral Components	K210566	MBH
LEGION Porous Tibia	K100897	MBH
Porous Tibia Baseplate	K211221	MBH
GENESIS II CR/PS	K951987, K962557	JWH
ANTHEM	K142807	JWH

Discussion of Similarities and Differences

This Traditional 510(k) submission supports an update to the CORI System to allow the system to be used with the CORI Knee TENSIONER (TENSIONER) and the associated software upgrade, CORI 1.7. The TENSIONER is an electromechanical accessory designed to provide feedback to CORI with respect to the force that the user applies to the joint during gap assessment. It is used by the surgeon in the gap planning stages of a total knee replacement procedure to provide a quantitative assessment of soft tissue laxity.

The modifications made to CORI do not impact the system's intended use, indications for use, or fundamental scientific technology.

Blue Belt Technologies believes that CORI is subject to premarket notification requirements under Section 510(k) of the Federal Food, Drug and Cosmetic Act ("FFDCA" or "the Act") and is substantially equivalent to the previously cleared REAL INTELLIGENCE CORI system, K220255, and the OMNIBotics Knee System, K200888.

Table 2: Predicate Device

Manufacturer	Description	Submission Number	Clearance Date
Blue Belt Technologies, Inc.	REAL INTELLIGENCE CORI	K220255	03/29/2022
Corin Ltd.	OMNIBotics Knee System	K200888	06/27/2020

Table 3: Summary of Technological Similarities with Predicate

Devices	Subject Device CORI	Primary Predicate CORI K220255	Secondary Predicate OMNIBotics Knee System K200888
Intended use and Indications for Use [Same]	Same as primary 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. 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, total knee arthroplasty, and total hip arthroplasty.	The OMNIBotics Knee System is indicated for stereotaxic surgery to aid the surgeon in locating anatomical structures and aligning endoprostheses with these anatomical structures during Total Knee Arthroplasty. The BalanceBot™ is indicated as a tool for adjustment of soft tissue and the femoral implant to reduce instability from flexion gap asymmetry. The OMNIBotics Knee System supports OMNI Apex Knee™ implants and CORIN Unity Knee™ implants.

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Devices	Subject Device CORI	Primary Predicate CORI K220255	Secondary Predicate OMNIBotics Knee System K200888
Technological Characteristics – Operating Principle [Same]	Same as primary predicate.	For knee applications, 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 with final bone surface for receiving the implant prepared using a standard surgical saw. 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. The 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 or tibial plateau in preparation for placement of the surgical implant. 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. To support the hip application, CORI uses a Virtual Machine with hypervisor to enable the Windows-based HIP7 software to run on CORI.	N/A

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Devices	Subject Device CORI	Primary Predicate CORI K220255	Secondary Predicate OMNIBotics Knee System K200888
Technological Characteristics – Tensioning Instrument [Substantially Equivalent]	The TENSIONER is an electromechanical tensioning instrument with reverse-action pliers to distract the joint.	Consists of a Gap Planning stage to assist users with (manual) ligament balancing.	The BalanceBot is an electro-mechanical tensioning instrument with integrated force sensors and position actuators.
Technological Characteristics – Gap Balancing [Substantially Equivalent]	The TENSIONER is used during the Gap Planning stage of the CORI Total Knee Arthroplasty application and provides feedback to CORI with respect to the force that the user applies to the joint to assist with ligament balancing.	Consists of a Gap Planning stage to assist users with (manual) ligament balancing.	BalanceBot assists the surgeon with ligament balancing during total knee arthroplasty.
Knee Implant Product Codes Supported [Same]	Same as primary predicate.	HSX, JWH, MBH	N/A
Environment of Use [Same]	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.	N/A

Non-Clinical Testing (Bench)

Design verification and validation testing demonstrated that CORI meets all design requirements and is as safe and effective as its primary predicate device (K220255) and secondary predicate device OMNIBotics Knee System (K200888). Comprehensive performance testing demonstrated that the system meets required design inputs. Performance data consisted of physical performance testing for all system components. Additionally, the following evidence was provided:

- Biocompatibility evaluation demonstrating that the system satisfies the requirements of *ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management process*.
- Safety and Electromagnetic Compatibility (EMC) testing demonstrating that the device complies with *IEC 60601-1 Medical Electric Equipment – Part 1: General Requirements for Basic Safety and Essential Performance* and *IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests*.
- 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 and TENSIONER in a simulated use environment. Human factors and usability engineering processes were followed per *IEC 62366-1:2015+A1:2020 Application of Usability Engineering to Medical Devices*.

All verification and validation testing concluded with acceptable results. Based on these test results, Blue Belt Technologies has concluded that all design inputs have been met and that the design verification and validation testing performed did not raise any new questions of safety or effectiveness.

Conclusions

The subject device, CORI, described in this submission has the same intended use and the same fundamental scientific technology as the primary predicate device, K220255. The primary difference between the subject device and CORI (K220255) is the update to allow the system to be used with TENSIONER and the associated software upgrade, CORI 1.7. The main functionality of the Total Knee Arthroplasty (TKA) software is the same as presented in K201022, with modifications to allow for communication with TENSIONER. The addition of TENSIONER does not change the system's method for gap calculation, which remains the same as the previously cleared devices.

While the technological characteristics differ between manual and a tool-assisted gap-balancing measurement, the questions regarding accuracy and implementation of intraoperative gap-balancing

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apply to both the subject and primary predicate device. Additionally, usability testing demonstrated that users are able to successfully perform gap balancing using TENSIONER and the CORI system; therefore, the difference of the technological characteristics does not introduce new questions of safety or effectiveness.

Blue Belt Technologies believes that FDA can find CORI to be substantially equivalent to the predicate devices, REAL INTELLIGENCE CORI system, K220255, and the OMNIBotics Knee System, K200888. The information presented in this 510(k) premarket notification demonstrates that CORI is as safe and effective as the primary predicate CORI system (K220255).