March 18, 2024

Herlinger Corrine
Senior Principal Regulatory Affairs Specialist
2828 Railroad Street
Pittsburgh, Pennsylvania 15222

Re: K240139
Trade/Device Name: Real Intelligence™ CORI™
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 17, 2024
Received: January 18, 2024

Dear Herlinger Corrine:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240139

Device Name
REAL INTELLIGENCE CORI

Indications for Use *(Describe)*

REAL INTELLIGENCE 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),
• revision knee arthroplasty, 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.

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Blue Belt Technologies, Inc.
2875 Railroad Street
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T: 412-683-3844
www.smith-nephew.com

510(k) Summary

510(k) Owner	Blue Belt Technologies, Inc. 2875 Railroad Street Pittsburgh, PA 15222 USA Tel: (412) 683-3844
Contact Person	Corrine Herlinger Senior Principal Regulatory Affairs Specialist Tel: 412.552.6428 Email: corrine.herlinger@smith-nephew.com
Date Prepared	March 14, 2024
Classification Reference	21 CFR 882.4560
Product Code	OLO
Supported Codes	HSX, JWH, MBH, NJD
Common/Usual Name	Orthopedic Stereotaxic Instrument
Trade/Proprietary Name	REAL INTELLIGENCE™ CORI™ (CORI)
Predicate Device(s)	REAL INTELLIGENCE™ CORI™ (K231963)
Reason for Submission	The purpose of this Traditional 510(k) submission is to seek clearance for a modification to CORI to integrate an image-based planning option into the Total Knee Arthroplasty (TKA) and Unicondylar Knee Replacement (UKR) applications.

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Intended Use

REAL INTELLIGENCE 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

REAL INTELLIGENCE 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),
- revision knee arthroplasty, 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. For knee applications, CORI aids the surgeon in planning the surgical implant location and in executing the surgical plan by controlling the cutting engagement of the surgical bur.

For knee applications, 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 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.

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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
SMITH & NEPHEW, INC. REVISION KNEE SYSTEM	K043440	JWH
REVISION KNEE SYSTEM	K041106	JWH
LEGION RK TIBIAL WEDGES (Hemi-Step & Full-Step)	K953274	JWH
LEGION COBALT CHROME REVISION KNEE SYSTEM	K060742	JWH
LEGION Knee System	K180334	JWH, MBH
ENGAGE Partial Knee System	K190439	NJD, HSX
JOURNEY II UK™ and ENGAGE™ Cementless Partial Knee System	K222653	NJD, HSX

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Discussion of Similarities and Differences

This Traditional 510(k) submission supports an update to integrate an image-based planning option into the TKA and UKR applications. The proposed modification to CORI will allow the CORI 3.0 software to import a pre-operative plan if desired by the surgeon.

The modifications made to support the change 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 (K221224).

Table 1: Predicate Device

Manufacturer	Description	Submission Number	Clearance Date
Blue Belt Technologies, Inc.	REAL INTELLIGENCE CORI	K231963	08/01/2023

Table 2: Summary of Technological Similarities with Predicate

Feature	Subject Device CORI	Primary Predicate CORI – K231963
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	Same as predicate.	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), • revision knee arthroplasty, and • total hip arthroplasty (THA).
Knee Implant Product Codes Supported	Same as predicate.	HSX, JWH, MBH, NJD
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.

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Feature	Subject Device CORI	Primary Predicate CORI – K231963
Technological Characteristics	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. CORI uses either pre-operative data (for image-based cases) or intraoperative data collection (for image-free or non-CT data generation cases) to create a model of the patient's femur and tibia in CORI tracking space and allows the surgeon to prepare/modify the 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 to shape the operative condyle 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.	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. CORI uses intraoperative data collection (image-free or non-CT data generation) to create a model of the patient's femur and tibia in CORI tracking space and allows the surgeon to prepare/modify 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 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.

Non-Clinical Testing (Bench)

Design verification and validation testing demonstrated that CORI meets all design requirements and is as safe and effective as its predicate device (K231963). Comprehensive testing demonstrated that the system meets required design inputs. Additionally, the following evidence was provided:

- 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 Device Software Functions*.
- Summative usability validation testing demonstrating that representative users were able to use the subject device safely and effectively in a simulated use environment. Human factors and usability engineering processes were followed per *IEC 62366 - Application of Usability Engineering to Medical Devices*.

Per Human Factors evaluation, updates made to the graphical user interface and software workflows for TKA and UKA in support of the RI.KNEE-v3.0.0 software were found to be safe and effective for the intended users, uses, and use environments. The study demonstrated that the surgeon users were able to safely and effectively perform tasks necessary to execute TKA and UKA procedures using the CORI system.

Conclusion

The subject device, CORI, described in this submission has the same intended use, indications for use, and fundamental scientific technology as the predicate device, CORI (K231963). The difference between the two systems is an update to CORI to integrate an image-based planning option into the Total Knee Arthroplasty (TKA) and Unicondylar Knee Replacement (UKR) applications. The proposed modification to CORI will allow the CORI 3.0 software to import a pre-operative plan if desired by the surgeon.

The key determining factor in establishing substantial equivalence is whether CORI can register the pre-operative plans safely and effectively. Comprehensive verification testing demonstrated that the system meets required design inputs. Summative usability validation testing established that representative users can use the subject device safely and effectively in a simulated use environment.

The information presented in this 510(k) premarket notification demonstrates that CORI with image-based planning is as safe and effective as the predicate device (K231963). Blue Belt Technologies believes that FDA can find CORI to be substantially equivalent to the predicate device.