March 26, 2026

Blue Belt Technologies, Inc.
Samantha Zanetti
Senior Regulatory Affairs Specialist
2875 Railroad St.
Pittsburgh, Pennsylvania 15222

Re: K260601
Trade/Device Name: Real Intelligence™ Cori™
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, HSX, JWH, MBH, NJD,
Dated: February 23, 2026
Received: February 24, 2026

Dear Samantha Zanetti:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260601

Device Name
REAL INTELLIGENCE™ CORI™ (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.

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

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510(k) Summary

510(k) Owner	Blue Belt Technologies, Inc. 2875 Railroad Street Pittsburgh, PA 15222 USA Tel: (412) 683-3844
Contact Person	Samantha Zanetti Senior Regulatory Affairs Specialist Tel: 856.408.4750 Email: Samantha.zanetti@smith-nephew.com
Date of Submission	February 23, 2026
Classification Reference	21 CFR 882.4560
Classification Name	Stereotaxic instrument
Product Code	OLO
Common/Usual Name	Orthopedic Stereotaxic Instrument
Trade/Proprietary Name	REAL INTELLIGENCE™ CORI™ (CORI)
Predicate Device(s)	REAL INTELLIGENCE™ CORI™ (K240139)
Reference Device(s)	REAL INTELLIGENCE™ CORI™ (K191223 and K221224)
Reason for Submission	The purpose of this Special 510(k) submission is to seek clearance for modifications to CORI to add feature enhancements to the Total Knee Arthroplasty and Unicondylar Knee Replacement software applications.

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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

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 Special 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.

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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 Special 510(k) submission supports an update for two modifications to the CORI software:

- Addition of a pre-operative planning screen that allows users to modify a pre-operative plan, prior to entering CORI's intraoperative workflow.
- Addition of a new widget to adjust cut planes during revision knee arthroplasty procedures utilizing the TKA application.

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 (K240139).

Table 1: Predicate Device

Manufacturer	Description	Submission Number	Clearance Date
Blue Belt Technologies, Inc.	REAL INTELLIGENCE CORI	K240139	March 18, 2024

Table 2: Summary of Technological Similarities with Predicate

Devices	Subject Device CORI	Primary Predicate CORI – K240139
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.	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).
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.

Devices	Subject Device CORI	Primary Predicate CORI – K240139
Technological Characteristics	Same as predicate.	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. CORI intraoperative 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. • **Speed control** regulates the signal going to the motor control module. When the surgeon encroaches on a portion of bone that is not to be cut, the robotic system will disable cutting by retracting the bur inside the guard or by limiting the speed of the drill.

The following reference devices were used to demonstrate well-established test methods:

Table 3. Reference Devices

Manufacturer	Description	Submission Number	Clearance Date
Blue Belt Technologies, Inc.	REAL INTELLIGENCE CORI	K191223	June 28, 2019
Blue Belt Technologies, Inc.	REAL INTELLIGENCE CORI	K221224	August 19, 2022

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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 (K240139). Comprehensive testing demonstrated that the system meets required design inputs. Summative usability testing (including labeling validation) demonstrated that participating surgeons were able to use the subject device safely and effectively in a simulated use environment.

Blue Belt Technologies has concluded that all design inputs have been met and that the 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, indications for use, and the same technological characteristics as the predicate device, CORI (K240139). The difference between the two systems is an update to CORI to add two modifications to the software; a pre-operative planning screen that allows users to modify a pre-operative plan during case-setup and prior to the intraoperative planning states, and a new widget to adjust cut planes during revision knee arthroplasty procedures.

The key determining factor in establishing substantial equivalence is whether the features added to CORI affect the safety and effectiveness of the TKA and UKR planning workflows. Comprehensive verification testing demonstrated that the system meets required design inputs. Summative usability testing results demonstrate 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 the ability to adjust the pre-operative plan and cut planes (within the TKA application) is as safe and effective as the predicate device (K240139). Blue Belt Technologies believes that FDA can find CORI to be substantially equivalent to the predicate device.