December 5, 2025

Blue Belt Technologies, Inc.
Amy Zhi
Sr. Regulatory Affairs Specialist
2875 Railroad St.
Pittsburgh, Pennsylvania 15222

Re: K252841
Trade/Device Name: REAL INTELLIGENCE™ CORI™ XT (CORI XT)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, HSX , JWH , MBH , KWS
Dated: September 5, 2025
Received: September 8, 2025

Dear Amy Zhi:

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.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252841

Please provide the device trade name(s).

REAL INTELLIGENCE™ CORI™ XT (CORI XT)

Please provide your Indications for Use below.

REAL INTELLIGENCE™ CORI™ XT 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,
- anatomic total shoulder arthroplasty (aTSA), and
- reverse total shoulder arthroplasty (rTSA).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Blue Belt Technologies, Inc. is a subsidiary of Smith & Nephew, Inc.

510(k) Summary

510(k) Owner	Blue Belt Technologies, Inc. 2875 Railroad Street Pittsburgh, PA 15222 USA Tel: (412) 683-3844
Contact Person	Amy Zhi Senior Regulatory Affairs Specialist Tel: 484.802.1185 Email: jie.zhi@smith-nephew.com
Date of Submission	September 05, 2025
Classification Reference	21 CFR 882.4560
Product Code	OLO
Supported Codes	HSX, JWH, MBH, KWS
Common/Usual Name	Orthopedic Stereotaxic Instrument
Trade/Proprietary Name	REAL INTELLIGENCE™ CORI™ XT (CORI XT)
Predicate Devices	Primary - REAL INTELLIGENCE™ CORI™ (K240139) Additional - ExactechGPS Total Shoulder Application, Equinoxe Planning Software (K213546)
Reason for Submission	The purpose of this submission is to seek clearance for the REAL INTELLIGENCE CORI XT robotic orthopedic surgical navigation and burring system.

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Intended Use

REAL INTELLIGENCE™ CORI™ XT 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™ XT 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,
- anatomic total shoulder arthroplasty (aTSA) and
- reverse total shoulder arthroplasty (rTSA).

Device Description

The subject of this Traditional 510(k) is REAL INTELLIGENCE CORI XT (CORI XT), a robotic orthopedic surgical navigation and burring system. Like its predecessor, REAL INTELLIGENCE CORI (K240139), CORI XT uses established technologies of navigation via a passive infrared tracking camera. CORI XT 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 XT 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 per the surgeon's plan, the robotic system will disable cutting by retracting the bur inside the guard or by limiting the speed of the drill. Alternatively, the surgeon can disable both cutting 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 XT:

Table 1: Currently Supported Smith+ Nephew Knee Implants

Implant Model Name	510(k) Number	Classification Product Code
JOURNEY II Unicompartmental Knee System	K191211	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

Currently Supported Shoulder Implants

The following Smith+Nephew shoulder implants are supported on CORI XT:

Table 2: Currently Supported Smith+ Nephew Shoulder Implants

Implant Model Name	510(k) Number	Classification Product Code
AETOS Implant system	K230572, K220847	KWS

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Discussion of Similarities and Differences

Blue Belt Technologies believes that CORI XT 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 primary predicate, REAL INTELLIGENCE CORI (K240139) and the secondary predicate device, ExactechGPS Total Shoulder Application (K213546).

Table 3: Primary Predicate Device

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

Table 4: Secondary Predicate Device

Manufacturer	Description	Submission Number	Clearance Date
Blue Ortho	ExactechGPS Total Shoulder Application, Equinoxe Planning Software	K213546	January 06, 2022

Table 5: Summary of Technological Similarities with Predicates

Feature	Proposed Device REAL INTELLIGENCE CORI XT	Primary Predicate Device REAL INTELLIGENCE CORI (K240139)	Additional Predicate Device ExactechGPS Total Shoulder Application, Equinoxe Planning Software (K213546)
Intended Use	REAL INTELLIGENCE CORI XT (CORI XT) 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 ExactechGPS is intended for use during preoperative planning and during orthopedic surgery to aid the surgeon in locating anatomical structures and aligning the endoprosthesis with the anatomical structures provided that the required anatomical landmarks can be identified on the patient's preoperative CT scan.
Indications for Use	REAL INTELLIGENCE CORI XT 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:	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:	The ExactechGPS Total Shoulder Planning Application is specifically indicated for pre-operative planning of Total Shoulder Arthroplasty using the Equinoxe system. The ExactechGPS Total Shoulder Planning Application permits to visualize, measure and reconstruct anatomical

	• unicondylar knee replacement (UKR), • total knee arthroplasty (TKA), • revision knee arthroplasty, • anatomic total shoulder arthroplasty (aTSA), and • reverse total shoulder arthroplasty (rTSA)	• unicondylar knee replacement (UKR), • total knee arthroplasty (TKA), • revision knee arthroplasty, and • total hip arthroplasty (THA).	structures in order to select and place the glenoid and humeral components. The ExactechGPS Total Shoulder Navigation Application is specifically indicated for Total Shoulder Arthroplasty using the Equinoxe system to aid the surgeon in locating anatomical structures and aligning the glenoid component with the anatomical structures.
Supported Product Codes	Supported Knee Product Codes: HSX, JWH, MBH Supported Shoulder Product Code: KWS	Supported Knee Product Codes: HSX, JWH, MBH, NJD	Supported Shoulder Product Code: KWS
Technological Characteristics	Same as primary 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.	N/A

Non-Clinical Testing (Bench)

Design verification and validation testing demonstrated that CORI XT meets all design requirements and is as safe and effective as its primary predicate device (K240139) and additional predicate device (K213546). Comprehensive performance 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*.
- Biocompatibility evaluation 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.*
- 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*.
- Accuracy and Usability Engineering Validation Testing demonstrating that representative users were able to use CORI XT safely and effectively in a simulated use environment through sawbone and cadaver models. Human factors and usability engineering processes were followed per *IEC 62366-1:2015+A1:2020 Application of Usability Engineering to Medical Devices*.

Per Human Factors evaluation, CORI XT has been found to be safe and effective for the intended users, uses, and use environments to support orthopedic surgeons in performing robotic Total Knee Arthroplasty (TKA), Unicondylar Knee Arthroplasty (UKA), Revision Knee Arthroplasty (RKA), anatomic Total Shoulder Arthroplasty (aTSA) and reverse Total Shoulder Arthroplasty (rTSA).

Conclusion

The subject device, CORI XT, described in this submission has the same intended use and fundamental scientific technology as the primary predicate device, CORI (K240139). CORI XT indications for use include: unicondylar knee replacement (UKR), total knee arthroplasty (TKA), revision knee arthroplasty, anatomic total shoulder arthroplasty (aTSA), and reverse total shoulder arthroplasty (rTSA). Inclusion of TSA procedures aligns with the additional predicate, ExactechGPS (K213546). Like ExactechGPS, CORI XT will aid the surgeon in the placement of glenoid and humeral components and support anatomic and reverse total shoulder arthroplasty.

The key determining factor in establishing substantial equivalence is whether CORI XT can accurately accomplish the desired bone cutting in accordance with the surgical plan. The comparative results of the cut-to-plan accuracy, indicate that CORI XT implant placement accuracy data is acceptable and equivalent to the primary predicate, CORI, for knee procedures, and the secondary predicate, ExactechGPS, for shoulder procedures. The usability testing results demonstrate that representative users are able to use the subject device safely and effectively in a simulated use environment. Blue Belt Technologies, Inc. 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.

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 Traditional 510(k) premarket notification demonstrates that CORI XT is as safe and effective as the predicate CORI (K240139) and additional predicate ExactechGPS Total Shoulder Application (K213546). Blue Belt Technologies believes that FDA can find CORI XT to be substantially equivalent to the primary and additional predicate devices.