February 14, 2020

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

Re: K193120
Trade/Device Name: Real Intelligence Cori
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 8, 2019
Received: November 12, 2019

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,

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K193120

Device Name
REAL INTELLIGENCE CORI (CORI)

Indications for Use *(Describe)*
Indications for use:
CORI is indicated for use in unicondylar knee replacement (UKR) surgical knee procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be determined.

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.***

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BLUE BELT TECHNOLOGIES

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# 510(k) Summary

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|---|---|
| 510(k) Owner | Blue Belt Technologies, Inc.<br>2905 Northwest Blvd Ste. 40<br>Plymouth, MN 55441 USA<br>Tel: (763) 452-4950<br>Fax: (763) 452-4675 |
| Contact Person | Corrine Herlinger<br>Principal Regulatory Affairs Specialist<br>Tel: (412) 683-3844 x 4128<br>Email: corrine.herlinger@smith-nephew.com |
| Date of Submission | November 8, 2019 |
| Classification Reference | 21 CFR 882.4560 |
| Product Code | OLO |
| Supported Codes | HSX |
| Common/Usual Name | Orthopedic Stereotaxic Instrument |
| Trade/Proprietary Name | REAL INTELLIGENCE◇ CORI◇ (CORI) |
| Predicate Device(s) | NAVIO Surgical System (NAVIO System) (K191223) |
| Reason for Submission | New Device |

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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 unicondylar knee replacement (UKR) surgical knee procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be determined.*

*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, to aid the surgeon in establishing a bone surface model for the target surgery and in planning the surgical implant location. Based on intraoperatively-defined bone landmarks and known geometry of the surgical implant, CORI aids the surgeon in establishing a bone surface model for the target surgery and planning the surgical implant location.

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 drill motor controller 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 Unicondylar Knee Implants

The following unicondylar knee implants are supported on CORI:

***Table 1: Currently Supported UKR Knee Implants***

| Implant Model Name | Manufacturer | 510(k) Number |
|---|---|---|
| JOURNEY II Unicompartmental Knee System | Smith and Nephew | K191211 |
| JOURNEY UNI | Smith and Nephew | K102069 |
| STRIDE Unicondylar Knee | Smith and Nephew | K123380 |
| ZUK Select Knee System | Smith and Nephew | K160738 |

## Discussion of Similarities and Differences

CORI is substantially equivalent to the predicate device, the NAVIO System (K191223). The intended use and the established technologies used to prepare bone for the attachment of implant components, including implant accuracy, is the same as the predicate device. The CORI UKR software application features a workflow that is nearly identical to the predicate device, cleared via K191223.

***Table 2: Summary of Technological Similarities with Predicate***

| | **Subject Device CORI [Subject]** | **Predicate Device NAVIO [K191223]** |
|---|---|---|
| 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. | The NAVIO surgical system 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 unicondylar knee replacement (UKR) surgical knee procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be determined.<br><br>CORI is indicated for use with cemented implants only. | The NAVIO system 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, patellofemoral arthroplasty, and total knee arthroplasty.<br>The NAVIO system is indicated for use with cemented implants only. |

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| | | |
|---|---|---|
| Supported Product Code(s) | HSX | HRY, HSX, JWH, KRR, NPJ |
| Environment of Use | CORI is intended to be used by trained medical professionals in a hospital or clinical setting equivalent to an orthopedic surgery suite. | The NAVIO system is intended for use by trained orthopedic surgeons in an orthopedic surgical suite. |
| Technological Characteristics | CORI uses established technologies to prepare bone for attachment of UKR implant components.<br>CORI uses intraoperative data collection (image-free or non-CT data generation) to create a model of the patient's femur and tibia and allows the surgeon to prepare a surgical plan.<br>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.<br>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. | The NAVIO system uses established technologies to prepare bone for attachment of UKR, PFA, or 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.<br>NAVIO 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.<br>The NAVIO 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, tibial plateau, or patellofemoral joint in preparation for placement of the surgical implant.<br>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.<br>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. |

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## Non-Clinical Testing (Bench)

Design verification and validation testing was performed to demonstrate that CORI meets all design requirements and is as safe and effective as its predicate device.

Comprehensive performance testing demonstrated that the system meets required design inputs. Performance data consisted of physical performance test for all system components and system accuracy testing. Additionally, the following test data was provided:

- **Biocompatibility testing** 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*.
- **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 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 same technological characteristics as the predicate device, the NAVIO system (K191223). The primary difference between the two systems is that CORI is a next-generation system designed to improve overall system usability and ergonomics, offer increased system performance, and reduce the dependency on outside vendor components. The differences in the system hardware and accessories do not raise any new questions of safety or effectiveness.

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The key determining factor in establishing substantial equivalence is whether CORI hardware and accessories 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 implant placement accuracy data is acceptable and equivalent to the UKR implant placement accuracy data for the NAVIO system. Usability engineering test results demonstrate that representative users are able to use the subject device safely and effectively in a simulated use environment. The information presented in this 510(k) premarket notification demonstrates that the redesigned system is substantially equivalent to the NAVIO system (K191223) and that CORI is as safe and effective as the predicate.