March 18, 2024

Smith & Nephew, Inc
Wilcox Miriam
Sr. Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

Re: K240113
Trade/Device Name: CORIOGRAPH Knee Pre-Op Plan
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 16, 2024
Received: January 16, 2024

Dear Wilcox Miriam:

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, 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.

Submission Number *(if known)*

K240113

Device Name

CORIOGRAPH Knee Pre-Op Plan

Indications for Use *(Describe)*

Intended Use
CORIOGRAPH Pre-Op Planning and Modeling Service is intended to provide pre-operative planning for surgical procedures based on patient imaging, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

Indications for Use
The CORIOGRAPH Pre-op Planning and Modeling Service is indicated for use for the following procedures:
- unicondylar knee replacement (UKR)
- total knee arthroplasty (TKA)

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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510(k) Summary

510(k) Owner	Smith & Nephew, Inc. 1450 Brooks Road Memphis, Tennessee 38116
Contact Person	Miriam Wilcox Senior Regulatory Affairs Specialist Email: miriam.wilcox@smith-nephew.com
Date Prepared	18-March-2023
Classification Reference	21 CFR 888.3030
Product Code	PBF
Supported Codes	JWH, MBH, OOG, HSX
Common/Usual Name	Orthopaedic Surgical Planning and Instrument Guides
Trade/Proprietary Name	CORIOGRAPH Knee Pre-Op Plan
Predicate Device(s)	VISIONAIRE UK Patient Matched Cutting Guides (K211512)
Reason for Submission	This Traditional 510(k) submission is seeking clearance for a new offering, CORIOGRAPH Knee Pre-Op Plan V1.0, a module of the CORIOGRAPH Pre-Op Planning and Modeling Service

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Intended Use

CORIOGRAPH Pre-Op Planning and Modeling Service is intended to provide pre-operative planning for surgical procedures based on patient imaging, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

Indications for Use

The CORIOGRAPH Pre-op Planning and Modeling Service is indicated for use for the following procedures:

- unicondylar knee replacement (UKR)
- total knee arthroplasty (TKA)

Device Description

The subject CORIOGRAPH Knee Pre-Op Plan is a medical function module within the CORIOGRAPH Pre-Op Planning and Modeling Service. This service is an additional offering being introduced by Smith & Nephew to allow for pre-operative planning for surgical procedures based on patient imaging for total knee arthroplasty (TKA) and unicondylar knee replacement (UKR). The CORIOGRAPH Knee Pre-Op Plans will be generated for specific patients and anatomy by Smith and Nephew personnel using the CORIOGRAPH Knee Pre-Op Plan Software System V1.0, which is the subject of this submission. The CORIOGRAPH Knee Pre-Op Plans will output bone models of the patient anatomy and will generate patient-specific pre-operative plans which may be used on the REAL INTELLIGENCE CORI Surgical System.

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Currently Supported Knee Implants

The CORIOGRAPH Knee Pre-Op Plan is compatible with implant systems aligned to those supported with the REAL INTELLIGENCE CORI Surgical System. Compatible implant systems and clearance numbers are provided in Table 1.

TABLE 1. CURRENTLY SUPPORTED SMITH+ NEPHEW KNEE IMPLANTS FOR THE CORIOGRAPH KNEE PRE-OP PLAN V1.0

Implant Model Name	510(k) Number	Classification Product Code
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
LEGION Knee System	K180334	JWH, MBH

REAL INTELLIGENCE CORI Surgical System Compatibility

The CORIOGRAPH Knee Pre-Op Plan is compatible with the following versions of the REAL INTELLIGENCE CORI surgical system.

TABLE 2. CURRENTLY SUPPORTED SURGICAL SYSTEM COMPATIBILITY FOR THE CORIOGRAPH KNEE PRE-OP PLAN V1.0

Device Name	Version	510(k) Number	Classification Product Code
REAL INTELLIGENCE CORI	3.0	K240139	HSX

Discussion of Similarities and Differences

The purpose of this Traditional 510(k) submission is to seek clearance for the CORIOGRAPH Knee Pre-Op Plan V1.0, which is a medical function module of the CORIOGRAPH Pre-Op Planning and Modeling Service. This Software as a Medical Device (SaMD) is based on the VISIONAIRE Patient-Matched Technology Software Process also used to generate preoperative plans and physical instruments by the predicate device VISIONAIRE Patient-Matched Cutting Guides (K211512).

The modifications made to the VISIONAIRE Patient-Matched Technology Software Process include an update to a software application to allow for:

- A new pre-operative planning workflow within the software application. This workflow will use the same implant database used on the CORI Surgical System.
- Added ability to detect if the case is intended for Visionaire Patient Matched Cutting Guide or for CORIOGRAPH Pre-operative planning from the surgeon inputs.

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- Added ability to create a .json file and pre-operative plan images as outputs for pre-operative planning workflow.
- Implementation of minor bug fixes.

The software planning tools and processes used for the CORIOGRAPH Knee Pre-Op Plan have similar intended use, indications for use and technological characteristics as the software planning tools used for the preoperative plans generated for surgeon concurrence in the predicate VISIONAIRE UK Patient Matched Cutting Guides (K211512).

Smith & Nephew believes that CORIOGRAPH Knee Pre-Op Plan V1.0 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 3. PREDICATE DEVICE

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc	VISIONAIRE UK Patient Matched Cutting Guides	K211512	09/16/2021

Substantial equivalence analysis for the CORIOGRAPH Knee Pre-Op Plan is provided in Table 4.

TABLE 4. SUBSTANTIAL EQUIVALENCE TABLE

Design Aspect Reviewed	**CORIOGRAPH Knee Pre-Op Plan** (Subject Device)	**VISIONAIRE UK Patient Matched Cutting Guides** (Predicate Device)	**Comparison**
510(k) Number	K240113	K211512 S.E. 09/16/2021	N/A
Manufacturer	Smith & Nephew, Inc.	Smith & Nephew, Inc.	**Same** as predicate

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Design Aspect Reviewed	CORIOGRAPH Knee Pre-Op Plan (Subject Device)	VISIONAIRE UK Patient Matched Cutting Guides (Predicate Device)	Comparison
Indications for Use	**Intended Use** CORIOGRAPH Pre-operative Planning Service is intended to provide pre-operative planning for surgical procedures based on patient imaging, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. **Indications for Use** The CORIOGRAPH Pre-operative Planning Service is indicated for use for the following procedures: • unicondylar knee replacement (UKR) • total knee arthroplasty (TKA)	Smith & Nephew's VISIONAIRE UK Patient Matched Cutting Guides are intended to be used as patient-specific surgical instrumentation to assist in the positioning of knee replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. The Smith & Nephew VISIONAIRE UK Patient Matched Cutting Guides are intended for use with the following existing Smith & Nephew, Inc. Knee Systems and their cleared indications for use: • Genesis II Knee System • Legion Knee System • Journey BCS Knee System • Journey II Knee System • JOURNEY II Unicompartmental Knee (JOURNEY II UK) System (K190085) The Smith & Nephew VISIONAIRE UK Patient Matched Cutting Guides are intended for single use only.	**Substantially equivalent** – Intended use is modified to reflect that the output is a software file instead of a physical patient-matched part. The indications for use are updated to reflect the surgical procedures instead of the specific implant systems. As the software output is used within the CORI surgical system, the device is not limited by manufacture of physical parts. Compatible Implant Systems will be disclosed in the case management portal
Target Population	Patients who are able to undergo an MRI safely, fit the indications, and do not present any contraindications for the existing knee implant system to which it is designed.	Patients who are able to undergo an MRI safely, fit the indications, and do not present any contraindications for the existing knee implant system to which it is designed.	**Same** as predicate
Target Anatomy	Knee	Knee	**Same** as predicate

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Design Aspect Reviewed	**CORIOGRAPH Knee Pre-Op Plan** (Subject Device)	**VISIONAIRE UK Patient Matched Cutting Guides** (Predicate Device)	**Comparison**
Where used	Professional healthcare facility	Professional healthcare facility	**Same** as predicate
Compatible Total Knee Systems	Genesis II CR Genesis II PS LEGION CR LEGION CR Porous LEGION CR Narrow Porous LEGION PS Journey II BCS Journey II CR Journey II XR Journey II BCS ROX Journey II CR ROX Journey II UK Journey Uni	Genesis II CR Genesis II PS LEGION CR LEGION PS Journey II BCS Journey II CR Journey II XR JOURNEY II Unicompartmental Knee (JOURNEY II UK)	**Substantially equivalent –** As a software device, compatible implant systems for the subject device are aligned with implants cleared for use with the CORI Surgical System, while compatible implants for the predicate device were defined by cleared product offerings for physical patient matched guides.
Design Type	Patient Matched	Patient Matched	**Same** as predicate
Output	Preoperative surgical plan provided in PDF for surgeon review. After surgeon acceptance of the plan parameters, PDF and/or software file is provided to be used as an input to robotic surgical system.	Preoperative surgical plan provided in PDF for surgeon review. After surgeon acceptance of the plan parameters, Physical Patient Matched Cutting Block is provided.	**Substantially equivalent** – Final output is a software file instead of a physical patient-matched cutting guide
Common Name	Orthopaedic Surgical Planning and Instrument Guides	Knee Prosthesis	**Substantially Equivalent** - Output of Pre-Operative plan is SaMD instead of a physical guide, therefore product code is updated to reflect output.
Device Class	Class II	Class II	**Same** as predicate
Device Classification Name and Reference	21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories.	21 CFR 888.3520- Knee Joint Femorotibial metal/polymer nonconstrained cemented prosthesis 21 CFR 888.3560- Knee Joint Patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis	**Substantially Equivalent** - Output of Pre-Operative plan is SaMD instead of a physical guide, therefore product code is updated to reflect output.
Panel Code	Orthopaedics/87	Orthopaedics/87	**Same** as predicate
Product Code	PBF	HSX OOG	**Substantially Equivalent** - Output of Pre-Operative plan is SaMD instead of a physical guide, therefore product code is updated to reflect output.

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Design Aspect Reviewed	**CORIOGRAPH Knee Pre-Op Plan** (Subject Device)	**VISIONAIRE UK Patient Matched Cutting Guides** (Predicate Device)	**Comparison**
Supported Product Code	JWH MBH OOG HSX	JWH MBH OOG HSX	**Same** as predicate

Non-Clinical Testing (Bench)

Verification and validation testing demonstrated the safety and effectiveness of the software applications used in the CORIOGRAPH Knee Pre-Op Plan and demonstrated the safety and effectiveness of the generated CORIOGRAPH Knee Pre-Op Plan when used as an input to the CORI Surgical System. Summative usability testing demonstrated that participating surgeons were able use the subject device safely and effectively in a simulated use environment. Smith and Nephew, 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.

Conclusion

The software tools and process used for CORIOGRAPH Knee Pre-Op Plan have similar intended use and indications for use and the same technological characteristics used in the software planning tools and processes used for the preoperative plans generated for the predicate VISIONAIRE UK Patient Matched Cutting Guides (K211512). The differences between the two systems include an update to support the implant database used by the CORI Surgical System as well as a modification of the output to include a JSON file and preoperative plan images for use on the CORI Surgical System.

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 the CORIOGRAPH Knee Pre-Op Plan System may be used to generate pre-operative plans for surgical procedures based on patient imaging. This information also demonstrates that the CORIOGRAPH Knee Pre-Op Plan system is as safe and effective as the software and planning process used in the predicate VISIONAIRE UK Patient Matched Cutting Guides (K211512). Smith and Nephew, Inc. believes that FDA can find CORIOGRAPH Knee Pre-Op Plan V1.0 to be substantially equivalent to the predicate device.