November 15, 2024

Blue Belt Technologies, Inc.
Chandler Caufield
Senior Regulatory Affairs Specialist
2875 Railroad Street
Pittsburgh, Pennsylvania 15222

Re: K242272
Trade/Device Name: CORIOGRAPH Pre-Op Planning and Modeling Services
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: PBF
Dated: July 31, 2024
Received: August 1, 2024

Dear Chandler Caufield:

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,

Tejen D. Soni -S

For
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)*
K242272

Device Name
CORIOGRAPH Pre-Op Planning and Modeling Services

Indications for Use *(Describe)*

Intended Use

CORIOGRAPH Pre-Op Planning and Modeling Services are intended to provide preoperative planning for surgical procedures based on patient imaging, provided that anatomic landmarks necessary for generating the plan are identifiable on patient imaging scans.

Indications for Use

The CORIOGRAPH Pre-op Planning and Modeling Services are indicated for use for the following procedures:

- Unicondylar Knee Replacement (UKR)
- Total Knee Arthroplasty (TKA)
- Primary 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Blue Belt Technologies, Inc.
2875 Railroad Street
Pittsburgh, Pennsylvania 15222
USA

T: 412-683-3844
www.smith-nephew.com

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, Pennsylvania 15222
Contact Person	Chandler Caufield Senior Regulatory Affairs Specialist Email: chandler.caufield@smith-nephew.com
Date Prepared	31-July-2024
Classification Reference	21 CFR 888.3030
Product Code	PBF
Supported Codes	JDI, KWZ, LPH, LWJ, LZO, MBL, MEH
Common/Usual Name	Orthopaedic Surgical Planning and Instrument Guides
Trade/Proprietary Name	CORIOGRAPH Pre-Op Planning and Modeling Services
Primary Predicate Device	CORIOGRAPH Knee Pre-Op Plan (K240113)
Secondary Predicate Device	RI.HIP Modeler (K212040)
Reason for Submission	This Traditional 510(k) submission is seeking clearance for a new offering CORIOGRAPH Hip Pre-Op Plan V1.0 and CORIOGRAPH Modeler V1.0, modules of the CORIOGRAPH Pre-Op Planning and Modeling Services V2.0.

Blue Belt Technologies, Inc.
2875 Railroad Street
Pittsburgh, Pennsylvania 15222
USA

T: 412-683-3844
www.smith-nephew.com

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

Intended Use

CORIOGRAPH Pre-Op Planning and Modeling Services are intended to provide pre-operative planning for surgical procedures based on patient imaging, provided that anatomic landmarks generating the plan 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)
- primary total hip arthroplasty (THA)

Device Description

The subject CORIOGRAPH Hip Pre-Op Plan and CORIOGRAPH Modeler are medical function modules within the CORIOGRAPH Pre-Op Planning and Modeling Services. These services are additional offerings being introduced by Blue Belt Technologies, Inc. to allow for pre-operative planning for surgical procedures based on patient imaging for primary total hip arthroplasty (THA). The CORIOGRAPH Hip Pre-Op Plan system will utilize Smith and Nephew personnel to generate patient specific bone models and preoperative plans for primary THA which will be viewable and editable on CORIOGRAPH Modeler 1.0. Together, CORIOGRAPH Hip Pre-Op Plan and CORIOGRAPH Modeler are the subject of this submission.

Blue Belt Technologies, Inc.
2875 Railroad Street
Pittsburgh, Pennsylvania 15222
USA

T: 412-683-3844
www.smith-nephew.com

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

Currently Supported Hip Implants

The CORIOGRAPH Hip Pre-Op Plan is compatible with implant systems provided in Table 1.

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

Implant System Name	510(k)
ANTHOLOGY HIP SYSTEM	K211176
CATALYSTEM	K240381
CPCS CEMENTED HIP SYSTEM	K970351 K211176
POLARSTEM	K203175 K211176
REDAPT MONOBLOCK REVISION FEMORAL SYSTEM	K211176
SL-PLUS AND SLR-PLUS CEMENTLESS FEMORAL HIP SYSTEM	K211176
SYNERGY HIP SYSTEM	K963509 K211176
FEMORAL HEADS	K021673 K211176
OR30 HIP SYSTEM	K220959 K232667
R3 ACETABULAR SYSTEM - STIKTITE SHELLS	K070756
R3 ACETABULAR SYSTEM	K211176
REDAPT ACETABULAR SYSTEM	K211176

Discussion of Similarities and Differences

The purpose of this Traditional 510(k) submission is to seek clearance for the CORIOGRAPH Hip Pre-Op Plan V1.0 and CORIOGRAPH Modeler V1.0, which are medical function modules of the CORIOGRAPH Pre-Op Planning and Modeling Services V2.0. This Software as a Medical Device (SaMD) is based on CORIOGRAPH Knee Pre-Op Plan V1.0 also used to generate preoperative plans (K240113) as well as the secondary predicate RI.HIP Modeler (K212040).

The software planning tools and processes used for the CORIOGRAPH Hip 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 CORIOGRAPH Knee Pre-Op Plan V1.0 (K240113) as well as in the secondary predicate RI.HIP Modeler (K212040).

Smith & Nephew believes that CORIOGRAPH Hip 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 primary predicate CORIOGRAPH Knee Pre-Op Plan V1.0 (K240113) and secondary predicate RI.HIP Modeler (K212040).

Blue Belt Technologies, Inc.
2875 Railroad Street
Pittsburgh, Pennsylvania 15222
USA

T: 412-683-3844
www.smith-nephew.com

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

TABLE 2. PRIMARY PREDICATE DEVICE

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	CORIOGRAPH Knee Pre-Op Plan V1.0	K240113	03/18/2024

TABLE 3. SECONDARY PREDICATE DEVICE

Manufacturer	Description	Submission Number	Clearance Date
Blue Belt Technologies Inc.	RI.HIP MODELER	K212040	03/11/2022

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

Blue Belt Technologies, Inc.
2875 Railroad Street
Pittsburgh, Pennsylvania 15222
USA

T: 412-683-3844
www.smith-nephew.com

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

TABLE 4. SUBSTANTIAL EQUIVALENCE TABLE

Design Aspect Reviewed	**CORIOGRAPH Hip Pre-Op Plan** (Subject Device)	**CORIOGRAPH Knee Pre-Op Plan** (Primary Predicate Device)	**RI.HIP Modeler** (Secondary Predicate Device)	**Comparison**
510(k) Number	K242272	K240113	K212040	N/A
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 generating the plan 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) • primary total hip arthroplasty (THA)	**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)	**Intended Use** The RI.HIP MODELER is intended for preoperative planning for primary total hip arthroplasty. RI.HIP MODELER is intended to be used as a tool to assist the surgeon in the selection and positioning of components in primary total hip arthroplasty. **Indications for Use** RI.HIP MODELER is indicated for individuals undergoing primary hip surgery.	**Substantially equivalent** – • New indication added for Total Hip Arthroplasty • Introduction of Hip Modules has made the services offered plural. • Anatomic landmarks necessary statement has changed from “alignment and positioning of implant” to “generating the plan”.

Blue Belt Technologies, Inc.
2875 Railroad Street
Pittsburgh, Pennsylvania 15222
USA

T: 412-683-3844
www.smith-nephew.com

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

Design Aspect Reviewed	**CORIOGRAPH Hip Pre-Op Plan** (Subject Device)	**CORIOGRAPH Knee Pre-Op Plan** (Primary Predicate Device)	**RI.HIP Modeler** (Secondary Predicate Device)	**Comparison**
Target Population	Patients who are able to undergo an CT safely, fit the indications, and do not present any contraindications for the existing hip 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.	The patient population is adults only.	**Substantially equivalent –** CORIOGRAPH Pre-Op Planning and Modeling Services is incorporating new modules that use an alternative imaging modality with potential patient restrictions. Therefore, the Target Population statement is being updated to reflect the broader applications.
Target Anatomy	Knee Hip	Knee	Hip	**Substantially equivalent –** CORIOGRAPH Pre-Op Planning and Modeling Services are expanding the offering to planning for Hip implants. Compatible implants for both primary predicate device and secondary predicate device are implants manufactured by Blue Belt Technologies, Inc.'s parent company Smith+Nephew.
Where used	Professional healthcare facility	Professional healthcare facility	Clinical Setting	**Same** as primary predicate
Compatible Total Knee Systems	Smith and Nephew Inc. Implants: 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)	Smith and Nephew Inc. Implants: 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)	N/A	**Same** as primary predicate

Blue Belt Technologies, Inc.
2875 Railroad Street
Pittsburgh, Pennsylvania 15222
USA

T: 412-683-3844
www.smith-nephew.com

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

Design Aspect Reviewed	**CORIOGRAPH Hip Pre-Op Plan** (Subject Device)	**CORIOGRAPH Knee Pre-Op Plan** (Primary Predicate Device)	**RI.HIP Modeler** (Secondary Predicate Device)	**Comparison**
Compatible Total Hip Systems	Smith and Nephew Inc. Implants: ANTHOLOGY HIP System CATALYSTEM CPCS Cemented Hip System POLARSTEM Standard Offset Stem POLARSTEM Lateral Offset Stem POLARSTEM Valgus Offset Stem REDAPT Monoblock Revision Femoral System SL-PLUS AND SLR-PLUS Cementless Femoral Hip System Femoral Heads OR3O Hip System R3 Acetabular System R3 Acetabular System Anteverted Liner R3 Constrained Liner SYNERGY Hip System	N/A	Smith and Nephew Inc. Implants: ANTHOLOGY Stem POLARSTEM Standard Offset Stem POLARSTEM Lateral Offset Stem POLARSTEM Valgus Offset Stem Femoral Heads R3 Acetabular System R3 Acetabular System Anteverted Liner R3 Constrained Liner OR3O Liner SYNERGY Hip system	**Substantially equivalent** to secondary predicate. CORIOGRAPH Pre-Op Planning and Modeling Services are expanding the CORIOGRAPH offering to planning for primary Total Hip Arthroplasty Hip implants. Compatible implants for both primary predicate device and secondary predicate device are implants manufactured by Blue Belt Technologies, Inc.'s parent company Smith+Nephew.
Design Type	Patient Matched	Patient Matched	Patient Matched	**Same** as predicate devices.
Input	Surgeon Preferences X-Ray MRI CT Scan	Surgeon Preferences X-Ray MRI	Surgeon Preferences X-Ray	**Substantially Equivalent**
Output	Preoperative surgical plan Simulation of implant position	Preoperative surgical plan	Simulation of implant position	**Substantially Equivalent –** Hip modules are generating a preoperative plan that the surgeon may use to drive clinical decisions which is similar to the Knee module. Computational modeling simulation is equivalent to Secondary Predicate Device RI.HIP MODELER.

Blue Belt Technologies, Inc.
2875 Railroad Street
Pittsburgh, Pennsylvania 15222
USA

T: 412-683-3844
www.smith-nephew.com

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

Design Aspect Reviewed	**CORIOGRAPH Hip Pre-Op Plan** (Subject Device)	**CORIOGRAPH Knee Pre-Op Plan** (Primary Predicate Device)	**RI.HIP Modeler** (Secondary Predicate Device)	**Comparison**
Common Name	Orthopaedic Surgical Planning and Instrument Guides	Orthopaedic Surgical Planning and Instrument Guides	System, Image Processing, Radiological	**Same** as primary predicate
Device Class	Class II	Class II	Class II	**Same** as primary predicate and secondary predicate
Device Classification Name and Reference	21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories.	21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories.	21 CFR 892.2050 - Medical image management and processing system.	**Same** as primary predicate
Panel Code	Orthopaedics/87	Orthopaedics/87	Radiology/90	**Same** as primary predicate
Product Code	PBF	PBF	LLZ	**Same** as primary predicate
Supported Product Code (Knee)	HSX JWH MBH OOG	HSX JWH MBH OOG	N/A	**Same** as primary predicate
Supported Product Code (Hip)	JDI KWZ LPH LWJ LZO MBL MEH	N/A	JDI KWZ LPH LWJ LZO MBL MEH	**Same** as secondary predicate

Non-Clinical Testing (Bench)

Verification and validation testing demonstrated the safety and effectiveness of the software applications used in the CORIOGRAPH Pre-Op Planning & Modeling Services V2.0. Summative usability testing demonstrated that participating surgeons were able use the subject device safely and effectively in a simulated use environment. In addition, the credibility evaluation demonstrated that the kinematic models and Activities of Daily Living (ADLs) utilized in the subject device are clinically relevant. 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.

Blue Belt Technologies, Inc.
2875 Railroad Street
Pittsburgh, Pennsylvania 15222
USA

T: 412-683-3844
www.smith-nephew.com

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

Conclusion

The software tools and process used for CORIOGRAPH Pre-Op Planning & Modeling Services V2.0 have similar intended use, indications for use and technological characteristics used in the software planning tools and processes used for the preoperative plans generated for the primary predicate CORIOGRAPH Knee Pre-Op Plan (K240113) and the secondary predicate RI.HIP Modeler (K212040).

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 Pre-Op Planning & Modeling Services V2.0, specifically the CORIOGRAPH Hip Pre-Op Plan System V1.0 and the CORIOGRAPH Modeler V1.0 may be used to generate pre-operative plans for surgical procedures based on patient imaging. This information also demonstrates that the CORIOGRAPH Pre-Op Planning & Modeling Services V2.0 are as safe and effective as the software and planning process used in the primary predicate CORIOGRAPH Knee Pre-Op Plan (K240113) and secondary predicate RI.HIP Modeler (K212040). Blue Belt Technologies, Inc. believes that FDA can find CORIOGRAPH Pre-Op Planning & Modeling Services V2.0 to be substantially equivalent to the primary and secondary predicate devices.