June 25, 2025

Blue Belt Technologies, Inc.
Corrine Herlinger
Senior Principal Regulatory Affairs Specialist
2875 Railroad Street
Pittsburgh, Pennsylvania 15090

Re: K250921
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: May 28, 2025
Received: May 28, 2025

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 (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

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)*
K250921

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)
- Primary Anatomic Total Shoulder Arthroplasty (aTSA)
- Primary Reverse Total Shoulder Arthroplasty (rTSA)

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	Blue Belt Technologies, Inc. 2875 Railroad Street Pittsburgh, Pennsylvania 15222
Contact Person	Corrine Herlinger Senior Principal Regulatory Affairs Specialist Email: corrine.herlinger@smith-nephew.com
Date Prepared	March 26, 2025
Classification Reference	21 CFR 888.3030
Product Code	PBF
Common/Usual Name	Orthopaedic Surgical Planning and Instrument Guides
Trade/Proprietary Name	CORIOGRAPH Pre-Op Planning and Modeling Services
Primary Predicate Device	CORIOGRAPH Pre-Op Planning and Modeling Services (K242272)
Secondary Predicate Device	Materialise SurgiCase Shoulder Planner (K242813)
Reason for Submission	The purpose of this Traditional 510(k) submission is to seek clearance for a proposed modification to the CORIOGRAPH Pre-Op Planning and Modeling Services (CORIOGRAPH) Indications for Use to add Primary Anatomic Total Shoulder Arthroplasty (aTSA) and Primary Reverse Total Shoulder Arthroplasty (rTSA) procedures.

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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 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)
- Primary anatomic Total Shoulder Arthroplasty (aTSA)
- Primary reverse Total Shoulder Arthroplasty (rTSA)

Device Description

CORIOGRAPH Pre-Op Planning and Modeling Services (CORIOGRAPH) are Software as a Medical Device (SaMD) that provide pre-operative planning for orthopedic surgical procedures based on patient imaging, surgeon preferences and implant geometry. CORIOGRAPH is comprised of several medical software systems (modules), and these modules share a set of non-medical function software applications called the Case Processing System.

CORIOGRAPH is a Software Medical Device System. The medical function modules share a graphic user interface where the surgeon provides their case preferences and patient imaging, retrieves PDF plans generated by the Pre-Op Plan modules, and launches the Modeler modules.

CORIOGRAPH Pre-Op Plan Modules

Using patient-specific information, patient imaging, and surgeon inputs, a pre-operative plan is generated by Smith+Nephew personnel. The plan provides initial alignment recommendations to the surgeon on implant placement based on the geometries of the implant and of the generated bone models.

CORIOGRAPH Hip Modeler and CORIOGRAPH Shoulder Modeler Modules

CORIOGRAPH Hip Modeler and CORIOGRAPH Shoulder Modeler are web-based software applications intended for surgeons to modify the patient-specific pre-operative plan and to evaluate the impact of the modifications through the impingement analysis tools such as Impingement-free Range-of Motion (ROM) and Activities of Daily Living (ADL) simulations.

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Currently Supported Implants

CORIOGRAPH is compatible with the following Smith+Nephew implant systems:

	Implant System Name	510(k)
Knee Implants	JOURNEY II Unicompartmental Knee System	K191211
	JOURNEY UNI	K102069
	JOURNEY II CR	K121443
	JOURNEY II BCS	K111711
	JOURNEY II XR	K141471, K152726
	LEGION CR/PS	K951987, K962557, K093746
	LEGION Porous CR Femoral Components	K073325, K091543
	LEGION Porous CR Narrow Femoral Components	K210566
	LEGION Porous Tibia	K100897
	Porous Tibia Baseplate	K211221
	GENESIS II CR/PS	K951987, K962557
	ANTHEM	K142807
	LEGION Knee System	K180334
Hip Implants	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
	OR3O HIP SYSTEM	K220959, K232667
	R3 ACETABULAR SYSTEM - STIKTITE SHELLS	K070756
	R3 ACETABULAR SYSTEM	K211176
	REDAPT ACETABULAR SYSTEM	K211176
Shoulder	AETOS Implant system	K230572, K220847

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Discussion of Similarities and Differences

The purpose of this Traditional 510(k) submission is to seek clearance for a proposed modification to the CORIOGRAPH Pre-Op Planning and Modeling Services (CORIOGRAPH) Indications for Use to add Primary Anatomic Total Shoulder Arthroplasty (aTSA) and Primary Reverse Total Shoulder Arthroplasty (rTSA) procedures. The proposed modifications introduce two new medical function modules in CORIOGRAPH v3.0: CORIOGRAPH Shoulder Pre-Op Plan (v1.0) and CORIOGRAPH Shoulder Modeler (v1.0).

CORIOGRAPH Pre-Op Planning & Modeling Services v3.0 has a similar intended use, indications for use, and technological characteristics as the primary predicate device, CORIOGRAPH Pre-Op Planning and Modeling Services (K242272) v2.0, and secondary predicate device, Materialise SurgiCase Shoulder Planner (K242813). CORIOGRAPH Shoulder Pre-Op Plan shares the same software and planning processes as used in the primary predicate device. The CORIOGRAPH Shoulder Modeler Application allows the surgeon to evaluate the plan with impingement-free ROM and ADL simulations, which is substantially equivalent to CORIOGRAPH Hip Modeler (K242272).

Table 1: Substantial Equivalence Table

	CORIOGRAPH Pre-Operative Planning Services v3.0 Subject Device	**CORIOGRAPH Pre-Operative Planning and Modeling Services v2.0 (K242272)** Primary Predicate	**Materialise Shoulder System / SurgiCase Shoulder Planner (K242813)** Secondary Predicate
Indications for Use	**Intended Use** CORIOGRAPH Pre-operative Planning Services are intended to provide pre-operative 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-operative Planning Services are indicated for use for the following procedures: • Unicondylar Knee Replacement (UKR) • Total Knee Arthroplasty (TKA) • Primary Total Hip Arthroplasty (THA) • Primary Anatomic Total Shoulder Arthroplasty (aTSA) • Primary Reverse Total Shoulder Arthroplasty (rTSA)	**Intended Use** CORIOGRAPH Pre-operative Planning Services are intended to provide pre-operative 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-operative Planning Services are indicated for use for the following procedures: • Unicondylar Knee Replacement (UKR) • Total Knee Arthroplasty (TKA) • Primary Total Hip Arthroplasty (THA)	**SurgiCase Shoulder Planner Indication for Use** SurgiCase Shoulder Planner is intended to be used as a pre-surgical planner for simulation of surgical interventions for shoulder orthopedic surgery. The software is used to assist in the positioning of shoulder components. SurgiCase Shoulder Planner allows the surgeon to visualize, measure, reconstruct, annotate, and edit pre-surgical plan data. The software leads to the generation of a surgery report along with a pre-surgical plan data file which can be used as input data to design the Materialise Shoulder Guide and Models.
Product Code	PBF	PBF	QHE
Target Anatomy	Knee Hip Shoulder	Knee Hip	Shoulder

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Target Population	CORIOGRAPH Pre-Op Planning and Modeling Services may be used for patients who are able to undergo an MRI, CT, or X-ray safely, fit the indications, and do not present any of the contraindications for the existing Smith+Nephew implant systems to which the plan is designed.	CORIOGRAPH Pre-Op Planning and Modeling Services may be used for patients who are able to undergo an MRI, CT, or X-ray safely, fit the indications, and do not present any of the contraindications for the existing Smith+Nephew implant systems to which the plan is designed.	Adults
Compatible Shoulder Implant Systems	AETOS Total Shoulder System AETOS Reverse Shoulder System	N/A	AETOS Total Shoulder System AETOS Reverse Shoulder System (This is a subset of the implants the Materialise System is compatible with - See K242813 for a complete list)
Pre-Op Plan Input	Knee Pre-Op Plan: • Surgeon Preferences • X-Rays • MRI Scan Hip Pre-Op Plan: • Surgeon Preferences • X-Ray (option) • CT Scan (option) Shoulder Pre-Op Plan: • Surgeon Preferences • CT Scan	Knee Pre-Op Plan: • Surgeon Preferences • X-Rays • MRI Scan Hip Pre-Op Plan: • Surgeon Preferences • X-Ray (option) • CT Scan (option)	CT Scan
Pre-Op Plan Output	Knee Pre-operative 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 CORI Surgical System. Hip/Shoulder Pre-operative 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 modeler module. Hip or Shoulder Modeler module may output a Surgeon Modified Pre-Op Plan based on initial plan generated by the Hip or Shoulder Pre-Op Plan Module.	Knee Pre-operative 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 CORI Surgical System. Hip Pre-operative 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 modeler module. Hip Modeler module may output a Surgeon Modified Pre-Op Plan based on initial plan generated by Hip Pre-Op Plan Module.	The SurgiCase Shoulder Planner allows for the creation of a glenoid and/or humeral pre-operative plan. The software leads to the generation of a surgery report along with a presurgical plan data file.

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Non-Clinical Testing (Bench)

Design verification and validation testing demonstrated that CORIOGRAPH Pre-Op Planning and Modeling Services (v 3.0) meets all design requirements and is as safe and effective as its primary and secondary predicate devices. Comprehensive testing demonstrated that the system, including the two new medical function modules, CORIOGRAPH Shoulder Pre-Op Plan (v1.0) and CORIOGRAPH Shoulder Modeler (v1.0), meet 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*.
- The credibility evaluation demonstrated that the kinematic models and Activities of Daily Living (ADLs) simulations utilized in the subject device are clinically relevant.
- Summative usability validation testing demonstrated that representative users were able to use the subject device safely and effectively in a simulated use environment. Human factors and usability engineering processes were followed per *IEC 62366 - Application of Usability Engineering to Medical Devices*.

The results of the Summative Usability/Human Factors Validation study provided objective evidence that the surgeon-facing aspects of CORIOGRAPH Shoulder Pre-Op Plan and CORIOGRAPH Shoulder Modeler have been designed for safe and effective use for the intended users, intended uses, and under the expected use conditions.

Conclusion

Verification testing demonstrated that the system meets required design inputs. Summative usability testing demonstrated that representative users could use the subject device safely and effectively under the expected use conditions. 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.

The information presented in this 510(k) premarket notification demonstrates that the CORIOGRAPH Pre-Op Planning & Modeling Services v3.0, specifically the CORIOGRAPH Shoulder Pre-Op Plan (v1.0) and CORIOGRAPH Shoulder Modeler (v1.0), may be used to generate pre-operative plans for surgical procedures based on patient imaging. Blue Belt Technologies, Inc. believes that FDA can find CORIOGRAPH Pre-Op Planning & Modeling Services V3.0 to be substantially equivalent to the primary and secondary predicate devices.