September 25, 2025

Stryker Instruments
Susanne Galin
Chief Regulatory Affairs Specialist
1941 Stryker Way
Portage, Michigan 49002

Re: K251971
Trade/Device Name: RPS Primary TKA Software; RPS Console; RPS Saw One; RPS Cable; RPS Saw Oscillating Tip Cartridge; RPS Console Cart Attachment; Ball Tip Pointer
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 26, 2025
Received: August 29, 2025

Dear Susanne Galin:

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)*
K251971

Device Name
RPS Primary TKA Software; RPS Console; RPS Saw One; RPS Cable; RPS Saw Oscillating Tip Cartridge; RPS Console Cart Attachment; Ball Tip Pointer

Indications for Use *(Describe)*
The Stryker Robotic Precision System (RPS) Primary TKA Software application, when used with the Stryker Guidance Systems, is intended to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to rigid anatomical structures during orthopedic procedures.

The RPS Primary TKA Software application is indicated for use in total knee arthroplasty (TKA) procedures in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified.

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.

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510(k) Summary

807.92(a)(1) Submitter Information	
510(k) Submitter	Stryker Instruments 1941 Stryker Way Portage, MI 49002 USA
Contact Information	Primary: Susanne Galin, RAC Chief Regulatory Affairs Specialist susanne.galin@stryker.com Secondary: Megan Guilbault Senior Staff Regulatory Affairs Specialist megan.guilbault@stryker.com
Date Summary Prepared	26 June 2025

807.92(a)(2) Name of Device(s)	
Trade Name(s) and Manufacturer	• Stryker Robotic Power System (RPS) Primary TKA Software (Stryker Instruments) • RPS Console, RPS Console Cart Attachment (Stryker Instruments) • RPS Cable (Stryker Instruments) • RPS Saw One (Stryker Instruments) • RPS Saw Oscillating Tip Cartridge (Stryker Instruments) • Ball Tip Pointer (Stryker Leibinger)
Classification Name	Orthopedic Stereotaxic Instrument
Device Class	Class II Premarket Notification, 21 CFR 882.4560
Product Code	OLO

807.92(a)(3) Legally marketed device(s) to which equivalence is claimed	
Predicate: Real Intelligence™ CORI™	K240139
Reference: Mako Total Knee Application	K241011
Reference: Ortho Guidance Precision Knee System	K233542

807.92(a)(4) Device Description

Stryker Robotic Power System (RPS) Overview

RPS is a total joint bone preparation system to support total knee arthroplasty (TKA) consisting of functionality for intraoperative planning, kinematic analysis, boundary control, and guided resection. The Complete Workflow allows for the placement of Stryker Triathlon CR/PS Total Knee Implants (cemented or cementless), and plans/resects all 6 primary femoral/tibial resections. The Quick-Cut Workflow allows for placement of implants with implant-specific cut guides requiring primary distal femoral and proximal tibial cuts.

A handheld robotic saw is guided via camera visualization in relation to patient anatomy and the surgical plan established intraoperatively. The robotic saw movement is partially controlled by the RPS Console which determines, based on surgical plan and localization data, how the saw actuators need to move within three degrees of freedom (elevation, pitch, roll) to maintain the planned cut plane. The surgeon controls the remaining degrees of freedom.

807.92(a)(5) Intended Use/Indications of Use of the Device

The Stryker Robotic Power System (RPS) Primary TKA Software application, when used with the Stryker Guidance Systems, is intended to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to rigid anatomical structures during orthopedic procedures.

The RPS Primary TKA Software application is indicated for use in total knee arthroplasty (TKA) procedures in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified.

807.92(a)(6) Summary of the Technological Characteristics of the Device Compared to the Predicate

Characteristic	Subject Device	Predicate Device
Intended Use	The Stryker Robotic Power System (RPS) Primary TKA Software application, when used with the Stryker Guidance Systems, is intended to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to rigid anatomical structures during orthopedic procedures.	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	The RPS Primary TKA Software application is indicated for use in total knee arthroplasty (TKA)	Indicated for use in surgical procedures in which the use of stereotactic surgery may be

	procedures in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified.	appropriate, and where reference to rigid anatomical body structures can be determined. These procedures include: • Unicondylar knee replacement (UKR) • Total knee arthroplasty (TKA) • Revision knee arthroplasty • Total hip arthroplasty (THA)
System Elements	• Cart mounted guidance systems • Anatomy and device trackers • Software application • Pointer • Console/Cart Attachment • Saw/Cable • Cutting Accessory – cartridge-style oscillating blade	• Guidance cart • Anatomy and device trackers • Software application • Pointer • Console • Drill/Cable • Foot pedal • Cutting Accessory - bur
Modes of Operation	• System set-up • Calibration • Anatomy registration • Initial limb evaluation • Implant planning • Navigated bone resection • Freehand bone resection • Trial/final implant evaluation	• System set-up • Calibration • Anatomy registration • Initial limb evaluation • Implant planning • Navigated bone resection • Freehand bone resection • Trial/final implant evaluation
Operating Principle	RPS uses established methods and technologies to prepare bone for attachment of identified TKA implants. The bone surface may also be prepared to receive 4-in-1 cutting guides for other implants. RPS uses intraoperative data collection to create a model of the patient's femur and tibia in the RPS tracking space and allows the surgeon to prepare and modify the surgical plan. RPS uses a tracked saw whose head sits atop three actuators that adjust the positioning/alignment of the cutting accessory based on its location as it approaches the	For knee applications, CORI uses established technologies to prepare bone for attachment of TKA implant components. The bone surface may also be prepared to receive 4-in-1 cut guides. CORI uses either pre-operative data (for image-based cases) or intraoperative data collection (for image-free or non-CT data generation cases) to create a model of the patient's femur and tibia in CORI tracking space and allows the surgeon to prepare/modify the surgical plan. The system uses predefined boundaries generated during the planning process to control the motion

	patient bone to be resected per the surgical plan. When actuators are unable maintain the cut plane due to gross positioning of the saw, the saw will not activate or will deactivate. When gross positioning of the saw is adequate for actuators to maintain the cut plane, the saw can be activated.	of the surgical bur and limit the amount of bone removed to shape the operative condyle or tibial plateau in preparation for placement of the surgical implant.
Preoperative Imaging Requirements	None – Uses image-free, intraoperative planning only	Preoperative/image-based or intraoperative/image-free planning available
Intended Users/Use Environment	RPS is intended to be used by trained medical professionals in an operating room setting of a hospital or ambulatory surgery center	CORI is intended to be used by trained medical professionals in a hospital or clinical setting equivalent to an orthopedic surgery suite.
Robotic Type	Semi-active	Semi-active
Compatible Implants	Triathlon CR/PS Total Knee Implants, cemented and cementless (Complete Workflow) Implants with implant-specific cut guide requiring primary distal femoral and proximal tibial cuts (Quick-Cut Workflow)	Smith+Nephew knee implants as defined in product labeling, cemented and cementless models
Robotic Handpiece Type	Saw	Drill
Robotic Handpiece Motion	Three degrees of freedom for pitch, elevation, and roll	Single degree of freedom – bur retracts to limit exposure
Cutting Accessory Type	Oscillating blade (cartridge-style)	Bur

807.92(b)(1) Nonclinical Testing to Support Submission

The function and performance of the subject devices have been evaluated through non-clinical design verification and validation testing. Additional testing was performed on the subject devices to ensure that they meet their design requirements. The results of the tests demonstrate that the subject devices meet the requirements for their intended use.

Accuracy

Overall system accuracy was evaluated and determined to be <2.0° limb alignment error, <2.0 mm gap attainment error, and cut error <1 mm and <1° (90% of values at 95% confidence).

Software
Software verification and validation testing was conducted as required by IEC 62304 and FDA Guidance *"Guidance for the Content of Premarket Submissions for Device Software Functions."* All requirements were met and no new questions of safety or effectiveness were identified.

Cybersecurity
Cybersecurity testing was conducted in accordance with FDA Guidance "*Cybersecurity of Networked Medical Devices Containing Off-the-Shelf Software (Jan 2025),*" FDA Guidance *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (Sep 2023),"* AAMI TIR57, and NIST SP 800-30 Rev.1. All requirements were met and no new questions of safety or effectiveness were identified.

Biocompatibility
Biocompatibility testing of patient-contacting components was conducted in accordance with ISO 10993-1. All requirements were met and no new questions of safety or effectiveness were identified.

Reprocessing/Sterilization
Reprocessing and sterilization validation (moist heat) covering critical devices was successfully performed in accordance with AAMI ST98, AAMI TIR12, ISO 17664-1, AAMI TIR39, AAMI ST70, ISO 17665-1, and FDA Guidance *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (2015)."* All requirements were met and no new questions of safety or effectiveness were identified.

Cleaning validation was performed for non-sterile devices was successfully performed in accordance with AAMI TIR12, AAMI ST98, ISO 17664-2, and FDA Guidance *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (2015)."* All requirements were met and no new questions of safety or effectiveness were identified.

Sterility Testing for terminally sterile RPS Saw Oscillating Tip Cartridge was successfully performed in accordance with BS EN 556-1, BS EN ISO 11137-1, BS EN ISO 11137-2, BS EN ISO 11137-3. All requirements were met and no new questions of safety or effectiveness were identified.

Shelf-Life Evaluation for Terminally Sterile RPS Saw Oscillating Tip Cartridge was successfully performed in accordance with ASTM F1980-21, ISO 11607-1. All requirements were met and no new questions of safety or effectiveness were identified.

Electrical Safety and EMC
Electrical Safety and EMC testing was successfully performed in accordance with IEC 60601-1, IEC 60601-1-2, IEC 60601-4-2, and IEC 80601-2-77. All requirements were met and no new questions of safety or effectiveness were identified.

Human Factors Evaluation

Human factors were evaluated in accordance with IEC 62366-1 and FDA Guidance *"Applying Human Factors and Usability Engineering to Medical Devices (2016)."* All requirements were met and no new questions of safety or effectiveness were identified.

807.92(b)(2) Clinical Testing
No clinical testing was required to support this submission.

807.92(b)(3) Conclusions Drawn from Testing Performed
The results of verification and validation testing were determined to be successful for all protocols and demonstrate the functionality, integrity, and safety and effectiveness of the subject devices are sufficient for their intended use. Test results for the subject devices support a determination of substantial equivalence to the predicate devices.

Substantial Equivalence Rationale
The subject devices, in comparison with the legally marketed predicates with supporting similarities in comparison to the two reference systems, have the same or equivalent intended use, indications for use, operating principle, technical characteristics, and functional outputs. Risk analysis and verification/validation testing support that any differences between the subject and predicate don't raise different types of questions of safety or effectiveness, and that the subject devices are at least as safe and effective as the predicate. A determination of substantial equivalence is supported.