March 21, 2025

Stryker Instruments
Leandra Burke
Staff Regulatory Affairs Specialist
1941 Stryker Way
Portage, Michigan 49002

Re: K243958
Trade/Device Name: Consolidated Operating Room Equipment (CORE) 2 Console
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, ERL, HWE, HBE
Dated: December 20, 2024
Received: December 23, 2024

Dear Leandra Burke:

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.

Submission Number *(if known)*

K243958

Device Name

Consolidated Operating Room Equipment (CORE) 2 Console

Indications for Use *(Describe)*

The Stryker Consolidated Operating Room Equipment (CORE) 2 Console is intended for use in the cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to orthopedic, dental, ENT (Ear, Nose, Throat), neuro, spine, and endoscopic applications. The console is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.
The CORE 2 Console is also indicated as an accessory to the Stryker Spine Guidance Software for stereotactic surgical procedures on the spine in adult and pediatric (adolescent) patients.

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 - K243958

807.92(a)(1) – Submitter Information	
510(k) Submitter:	Stryker Instruments 1941 Stryker Way, Portage, MI 49002, USA
Contact Information:	Leandra Burke Staff Regulatory Affairs Specialist Tel: (269) 823-4639 Email: leandra.burke@stryker.com
Date Summary Prepared:	20 December 2024

807.92(a)(2) – Name of Device	
Trade Name:	Consolidated Operating Room Equipment (CORE) 2 Console
Classification Name:	Orthopedic Stereotaxic Instrument
Device Class:	Class II (21 CFR 882.4560)
Product Code(s):	OLO (Secondary ERL, HWE, HBE)

807.92(a)(3) – Legally marketed device to which equivalence is claimed
CORE 2 Console (K241171)
807.92(a)(4) – Device Description
The CORE 2 Console is a non-sterile, 120V AC-powered, reusable device that is intended for use outside of the sterile environment during surgery. The console supplies 40V DC power to a range of motors for use in a variety of surgical procedures as described in its labeling. It also provides a means for irrigation through an integrated irrigation pump. The console has three motor ports, two footswitch ports, and one irrigation cassette port. CORE 2 receives identification and configuration information from connected devices including Stryker handpieces, footswitches, cutting attachments with RFID, and irrigation cassettes. The console allows further device configuration through its graphical user interface (GUI). The primary modules that comprise CORE 2 are its power supply, central processing unit, motor controller, irrigation pump controller, RFID module, liquid crystal display (LCD) screen and speaker, touchscreen, USB interface, and an Ethernet interface. The software of the CORE 2 is responsible for the integration of these modules and control of the console. The console's software receives identification and configuration information from connected devices. This information is monitored and processed based on current system configurations, and can be used to activate handpiece motors, change motor speed, and activate or deactivate irrigation, among other functions. The device modifications in scope of this premarket notification consist of updates to the CORE 2 software to allow for its use within a RISE (Reimagining Integrated Surgical Experience) ecosystem. RISE is an optional software functionality that allows for Ethernet-based communication between

compatible Stryker devices (i.e., Connected OR Hub, SDC4K Information Management System, and Sonopet iQ consoles) and utilizes the DCM (Device Communication Module) protocol.

RISE provides for an integrated OR (Operating Room) solution to healthcare facilities to simplify workflows and reduce OR clutter. In a RISE configuration, adjustment of CORE 2 power, irrigation, and handpiece settings can be made directly on a Connected OR Hub / SDC4K GUI, thereby allowing the user to input commands via a single console. RISE functionality also allows for the activation of the subject device output via a remotely connected foot pedal. The functional output tasks that the software performs are the same as that of the predicate device.

807.92(a)(5) – Intended Use of the Device

Indications for Use

The Stryker Consolidated Operating Room Equipment (CORE) 2 Console is intended for use in the cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to orthopedic, dental, ENT (Ear, Nose, Throat), neuro, spine, and endoscopic applications. The console is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

The CORE 2 Console is also indicated as an accessory to the Stryker Spine Guidance Software for stereotactic surgical procedures on the spine in adult and pediatric (adolescent) patients.

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

There have been no changes made to the intended use, indications for use, design, materials, or fundamental scientific technology of the CORE 2 Console. The device has undergone a software modification to enable its use within a RISE ecosystem. The following table identifies technological characteristics shared between the subject and predicate devices.

Feature	Predicate Device (K241171)	Subject Device
Indication(s)	The Stryker Consolidated Operating Room Equipment (CORE) 2 Console is intended for use in the cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to orthopedic, dental, ENT (Ear, Nose, Throat), neuro, spine, and endoscopic applications. The console is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices. The CORE 2 Console is also indicated as an accessory to the	Same

	Stryker Spine Guidance Software for stereotactic surgical procedures on the spine in adult and pediatric (adolescent) patients.	
Conditions of Use	Non-sterile, reusable, outside of sterile environment during surgeries.	Same
For Use With	Various handpieces, footswitches, irrigation cassettes, and bone mill.	Same
Outer Profile	Bench-top style console with a liquid crystal display screen and irrigation pump (use of pump is optional). Coated sheet metal housing.	Same
Dimensions (W x D x H) Weight	13.0 x 17.4 x 5.4” 17.3lbs	Same
Energy Source	AC powered from mains supply through detachable cord	Same
Internal PCBAs (Hardware)	Four-channel RFID module, irrigation pump controller, main controller, power button, motor controller, handpiece / footswitch, port illumination	Same
User Interface	Color LCD screen allows the user to set the desired operating parameters. Capacitive touchscreen interface with GUI workflow.	Same
Irrigation	Forced, via peristaltic pump	Same
Connectivity	Ethernet port – service, connection for communication with compatible Stryker devices	Same

The following differences between the subject and predicate devices were considered in the determination of substantial equivalence:

- CORE 2 software update to enable its use within a RISE ecosystem.
- Additional mapping indicators for handpiece and footswitch ports.

807.92(b)(1) – Nonclinical Testing to Support Submission
The following testing was conducted to demonstrate that the modifications to the subject device are as safe and effective as the predicate:

- Software and wireless technology testing per FDA guidance documents and recognized standards
- EMC and Electrical Safety testing per FDA recognized standards
- Bench testing per various internal protocols
- Simulated use testing per various internal protocols
- Human factors testing per FDA guidance documents and recognized standards

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

807.92(b)(3) – Conclusions Drawn from Testing Performed
Results of performance testing demonstrate that the functionality, integrity, and safety and effectiveness of the subject device is sufficient for its intended use. Verification test results for the CORE 2 Console confirm that the differences in technology raise no new issues of safety or effectiveness when compared to the predicate device.

Conclusion/ Substantial Equivalence (SE) Rationale:
The subject devices, in comparison with the legally marketed predicate, has the same intended use, indications for use, operating principles, energy source, and functional outputs. Performance testing and risk analysis demonstrate that the device is as safe and effective as the predicate device and support a determination of substantial equivalence.