January 16, 2025

Stryker Instruments
Megan Guilbault
Staff Regulatory Affairs Specialist
1941 Stryker Way
Portage, Michigan 49002

Re: K242834
Trade/Device Name: System 9 Sterile Battery Container
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: September 19, 2024
Received: September 19, 2024

Dear Megan Guilbault:

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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.01.16 20:37:15 -05'00'

for: Christopher K. Dugard
Assistant Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and Infection Control 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)*

K242834

Device Name

System 9 Sterile Battery Container

Indications for Use *(Describe)*

The Stryker System 9 Sterile Battery Container is a reusable rigid sterilization container intended to allow for sterilization, by hospitals, surgery centers, and healthcare facilities, of the enclosed, compatible Stryker Sterile Battery Packs and maintain sterility of the enclosed device until used. The container is validated for use with compatible battery packs in low temperature hydrogen peroxide sterilization cycles.

Validated Low Temperature Hydrogen Peroxide Sterilization Cycles:
Load Configuration Cycles

System 9 Sterile Battery Container Bundle, Small:
STERRAD NX Standard cycle
STERRAD 100NX Standard cycle
STERRAD 100S short cycle
Steris V-PRO maX Lumen cycle
Steris V-PRO maX 2 Lumen cycle
Steris V-PRO 60 Lumen cycle
Steris V-PRO s2 Lumen cycle

System 9 Sterile Battery Container Bundle, Large:
STERRAD NX Standard cycle
STERRAD 100NX Standard cycle
STERRAD 100S short cycle
Steris V-PRO maX Lumen cycle
Steris V-PRO maX 2 Lumen cycle
Steris V-PRO 60 Lumen cycle
Steris V-PRO s2 Lumen cycle

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.

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"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."

1.0 Submitter Information

1.1 This Premarket Notification is submitted by:

Stryker Instruments
1941 Stryker Way
Portage MI 49002 USA

1.2 Contact Information

Contact name: Megan Guilbault
Cellular Telephone: (401) 241-6152
Email: megan.guilbault@stryker.com
Date Prepared: January 15, 2025

1.3 Device Name

Table 1: Subject Device Information

Subject Device Information	
Trade/Proprietary Name	System 9 Sterile Battery Container
Common Name	Sterilization Container Wrap
Classification	Class II
Classification Product Code	KCT
Classification Name	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Classification Regulation	21 CFR 880.6850
Review Panel	General Hospital

1.4 Predicate Device

Table 2: Predicate Device Information

Predicate Device Trade Name	**510(k) Number**	**Product Code**	**Manufacturer**
Aesculap Aicon™ Container	K214041	KCT	Aesculap, Inc.

1.5 Device Description

The Stryker System 9 Sterile Battery Container is a rigid, reusable device intended to enclose compatible Stryker sterile battery packs for hydrogen peroxide sterilization. The container consists of a stainless-steel perforated lid with a stainless-steel filter retention plate and a plastic (Radel®) base. The Sterile Battery container utilizes single use polypropylene filters and indicator cards. The container base is designed to exclusively fit onto the Stryker sterile battery charger to allow the sterile battery pack to charge while maintaining a sterile barrier. The Stryker System 9 Sterile Battery Container encompasses one distinct configuration in two sizes, small and large.

1.6 Indications for Use

The Stryker System 9 Sterile Battery Container is a reusable rigid sterilization container intended to allow for sterilization, by hospitals, surgery centers, and healthcare facilities, of the enclosed, compatible Stryker Sterile Battery Packs and maintain sterility of the enclosed device until used. The container is validated for use with compatible battery packs in low temperature hydrogen peroxide sterilization cycles.

Validated Low Temperature Hydrogen Peroxide Sterilization Cycles:

Load Configuration	Cycles
System 9 Sterile Battery Container Bundle, Small	STERRAD NX Standard cycle
	STERRAD 100NX Standard cycle
	STERRAD 100S short cycle
	Steris V-PRO maX Lumen cycle
	Steris V-PRO maX 2 Lumen cycle
	Steris V-PRO 60 Lumen cycle
	Steris V-PRO s2 Lumen cycle
System 9 Sterile Battery Container Bundle, Large	STERRAD NX Standard cycle
	STERRAD 100NX Standard cycle
	STERRAD 100S short cycle
	Steris V-PRO maX Lumen cycle
	Steris V-PRO maX 2 Lumen cycle
	Steris V-PRO 60 Lumen cycle
	Steris V-PRO s2 Lumen cycle

1.7 Comparison of Technological Characteristics

A comparison of the technological characteristics of the subject devices included in the scope of this Traditional 510(k) is included in Table 3 below.

Table 3: Technological Comparison

Description	Subject Device	Predicate Device	Discussion
	System 9 Sterile Battery Container	**Aesculap AICON™ Container**	
Intended Use	The Stryker System 9 Sterile Battery Container is a reusable rigid sterilization container	A device intended to be used to enclose another medical device that is to	**Similar**

Description	Subject Device System 9 Sterile Battery Container	Predicate Device Aesculap AICON™ Container	Discussion
	intended to allow for sterilization, by hospitals, surgery centers, and healthcare facilities, of the enclosed, compatible Stryker Sterile Battery Packs and maintain sterility of the enclosed device until used.	be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.	
Classification	Class II	Class II	**Identical**
Product Code	KCT	KCT	**Identical**
Condition of Use	Professional Use Only, Reusable, for use in a healthcare facility	Professional Use Only, Reusable, for use in a healthcare facility	**Identical**
Patient Population	Not intended for direct patient contact	Not intended for direct patient contact	**Identical**
Operating Principle	The user loads Stryker Sterile Battery Packs into the Sterile Battery Container Base. The Sterile Battery Container Lid with installed filter and filter retention plate is attached to the Sterile Battery Container Base, the external latching mechanism is closed, and the Tamper-Evident Lock is placed on the outside latch. The lid, filter, filter retention plate, and base all generate a sterile barrier. The loaded container becomes sterile once it has been run through a low-temperature hydrogen peroxide sterilizer. The indicator strips color-change mechanism is used to verify successful sterilization. Once sterilized, the container maintains sterility until opened, up to 45 days.	The user places instruments inside the container in a manner to allow proper sterilant penetration. The container lid is closed securely with a locking mechanism to ensure airtight seal. The container is placed in the sterilization chamber (under various sterilization modalities). After completion of appropriate sterilization cycle, verification of sterilization is conducted using indicator strips color-change mechanism. The containers are then stored in a clean, dry environment to maintain sterility and opened in a sterile area when ready to use. Once sterilized the container maintains	**Identical**

Description	Subject Device System 9 Sterile Battery Container	Predicate Device Aesculap AICON™ Container	Discussion
		sterility for 365 days or until opened.	
Sterilization Method	Low-temperature hydrogen peroxide sterilization • STERRAD NX Standard cycle • STERRAD 100NX Standard cycle • STERRAD 100S Short cycle • Steris V-PRO maX Lumen cycle • Steris V-PRO maX 2 Lumen cycle • Steris V-PRO 60 Lumen cycle • Steris V-PRO s2 Lumen cycle	• Low-temperature hydrogen peroxide sterilization • Steam Sterilization • STERIS V-PRO maX/maX 2: Lumen, Non-Lumen, Flex • STERIS V-PRO 60: Lumen, Non- Lumen, Flex • STERRAD 100NX: Standard, Express, Flex, Duo • STERRAD NX: Standard, Advanced • STERRAD l00S • STERIZONE VP4 • EtO	**Similar**
Container Base Material	Radel® PPSU Polyphenylsulfone	Anodized Aluminum	**Different** The predicate device is made from material that is compatible with a variety of sterilization methods. As the subject device is only being cleared with hydrogen peroxide sterilization, Stryker has chosen material suitable for the specific sterilization method and to prevent interference for wireless charging between the

Description	Subject Device System 9 Sterile Battery Container	Predicate Device Aesculap AICON™ Container	Discussion
			battery and charger. Verification and Validation Testing confirms that the subject device is safe and effective for its intended use and the differences do not raise different types of questions of Safety and Effectiveness.
Container Lid Material	Stainless Steel	Anodized Aluminum	**Different** The predicate device is made from material that is compatible with a variety of sterilization methods. As the subject device is only being cleared with hydrogen peroxide sterilization, Stryker has chosen material suitable for the specific sterilization method. Verification and Validation Testing confirms that the subject device is safe and effective for its intended use and the differences do not raise different types of questions of

Description	Subject Device System 9 Sterile Battery Container	Predicate Device Aesculap AICON™ Container	Discussion
			Safety and Effectiveness.
Filter Material	Polypropylene (Single Use)	Polypropylene (Single Use)	**Identical**
Maintenance of Sterility	45 Days	365 Days	**Different** The predicate device maintains a sterile barrier on the shelf for 365 days, whereas the subject maintains a sterile barrier for 45 days. Testing did not raise any different types of questions of Safety and Effectiveness.
Device Size	Small: 3.2” H x 4.2” W x 12.9” L Large: 3.9” H x 4.2” W x 12.9” L	Full size: 4” H x 11 ¾” W x 23 5/8” L Full size: 6” H x 11 ¾” W x 23 5/8” L Full size: 8” H x 11 ¾” W x 23 5/8” L Full size:10” H x 11 ¾” W x 23 5/8” L Three-Quarter: 4” H x 11 ¾” W x 18 3/8” L Three-Quarter: 6” H x 11 ¾” W x 18 3/8” L Three-Quarter: 8” H x 11 ¾” W x 18 3/8” L Three-Quarter:10” H x 11 ¾” W x 18 3/8” L	**Different** The predicate offers a larger range of sizes while the subject device is designed to specifically be used with the System 9 Sterile Batteries, which are available in two sizes, small and large. Verification testing confirms that the subject device is safe and effective for its intended use and the differences do not raise different types of questions of Safety and Effectiveness.

Description	Subject Device System 9 Sterile Battery Container	Predicate Device Aesculap AICON™ Container	Discussion
		Half size: 4” H x 11 ¾” W x 11 7/8” L Half size: 6” H x 11 ¾” W x 11 7/8” L Half size: 8” H x 11 ¾” W x 11 7/8” L Half size: 10” H x 11 ¾” W x 11 7/8” L	
Container Design	Solid Bottom Perforated Lid with filter retention plates and single use polypropylene filters Gasket	Solid Bottom Perforated Lid with filter retention plates and single use polypropylene filters Gasket	**Identical**

1.8 Summary of Non-Clinical Testing

The intended use of the subject device and the predicate device are identical, and the technological characteristics are similar. The differences between the two devices do not raise any new or different types of questions of safety and effectiveness.

Risk management was conducted in accordance with ISO 14971.

A suite of non-clinical testing was performed in accordance with applicable standards. See table below:

Table 4: Performance Testing

Testing	Standard in compliance with	Acceptance Criteria	Results
Sterilization Efficacy	ISO 14937:2009 ISO 22441:2022	Confirms sterile efficacy	Pass
Toxicological Risk Assessment	ISO 10993-17	Confirms acceptable residuals	Pass

Testing	Standard in compliance with	Acceptance Criteria	Results
Cleaning Validation	AAMI ST98:2022	Cleaning instructions were validated and demonstrated that the subject devices could be visually and quantifiably cleaned	Pass
Maintenance of Sterility	AAMI ST77:2013/(R)2018	Demonstrates that the subject device is capable of maintaining product sterility for the duration of the shelf life	Pass
Simulated Use Design Validation	ISO 17664-1:2021 AAMI TIR 12:2020 ST77:2013/(R)2018	Confirms that the device can undergo repeated processing to support that the device's critical functionality or performance is maintained following a minimum number of exposures to the proposed sterilization methods	Pass
Human Factors Engineering	IEC 62366-1 Ed 1.1 b 2020	Confirms safety and effectiveness of the subject device for the intended users, uses, and use environments	Pass

Performance testing was performed in compliance with the following standards:

- ISO 14937:2009 - Sterilization of health care products – Low temperature vaporized hydrogen peroxide – Requirements for the development, validation and routine control of a sterilization process for medical device
- ISO 22441:2022 - Sterilization of health care products – Low temperature vaporized hydrogen peroxide – Requirements for the development, validation and routine control of a sterilization process for medical device
- ISO 10993-17:2003 – Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituents
- ISO 17664-1:2021 - Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices.
- AAMI TIR 12:2020 - Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers
- AAMI ST98:2022 -Cleaning validation of health care products – Requirements for development and validation of a cleaning process for medical devices
- AAMI ST77:2013/(R)2018 - Containment devices for reusable medical device sterilization.
- IEC 62366-1 Ed 1.1 b 2020 - Medical Devices – Part 1: Application of Usability Engineering to Medical Devices

1.9 Summary of Clinical Testing

Clinical testing was not required for this Traditional 510(k).

1.10 Conclusion

The conclusions drawn from the nonclinical and clinical tests demonstrate that the Stryker System 9 Sterile Battery Container is as safe, as effective, and performs as well as or better than the legally marketed device.