June 27, 2024

IDEATE Medical, Inc.
% Kevin Corrigan
Regulaory Consultant
Corrigan Regulatory Consulting
P.O. Box 6284
Anaheim, California 92816

Re: K233762
Trade/Device Name: SteroScope® Sterilization Technology System
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: Class II
Product Code: MLR
Dated: November 22, 2023
Received: November 24, 2023

Dear Kevin Corrigan:

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 and Part 809); 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.

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,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
Assistant Director
DHT4B: Division of Infection Control

and Plastic and Reconstructive Surgery 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233762

Device Name
SteroScope® Sterilization Technology System

Indications for Use *(Describe)*
The SteroScope® Sterilization Technology System is indicated for the terminal sterilization of cleaned reusable Flexible Endoscopes with up to 8 internal lumens with lumen dimensions of:

- ID of 1.0 mm or larger and a length of 3580 mm or shorter and
- ID of 1.2 mm or larger and a length of 4095 mm or shorter

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
K233762

26 June 2024

I. SUBMITTER

IDEATE Medical, Inc.
2821 N. Ballas Road C55
St. Louis, MO 63131

Phone: 760-402-8322

Contact Person: William Wong, CEO
bill.wong@ideatemedical.com

II. DEVICE

Name of Device:	SteroScope® Sterilization Technology System
Common Name:	Vaporized Hydrogen Peroxide Sterilizer
Classification Name:	Ethylene oxide gas sterilizer (21 CFR 888.6860)
Regulatory:	Class II
Product Code:	MLR, Sterilizer, Chemical

III. PREDICATE DEVICE

STERRAD 100NX DUO Cycle (K111377)

Reference Device: STERRAD 100NX EXPRESS Cycle (K092622)

IV. DEVICE DESCRIPTION

The SteroScope® Sterilization Technology System is a vaporized hydrogen peroxide based (VHP) sterilizer for the terminal sterilization of flexible endoscopes with the following characteristics:
Flexible Endoscopes with up to 8 internal lumens with lumen dimensions of:
• ID of 1.0 mm or larger and a length of 3580 mm or shorter and
• ID of 1.2 mm or larger and a length of 4095 mm or shorter.

The SteroScope® Sterilization Technology System is a Gas Plasma VHP sterilization system designed specifically for flexible endoscope terminal sterilization, not for general surgical instrument loads. It is a self-contained stand-alone system of hardware and software system that uses technology to rapidly diffuse VHP into all the channels of the flexible endoscope to facilitate the sterilization of inner device surfaces, while being occupationally and environmentally safe to use. To enable the terminal sterilization of long multi-lumen endoscopes, while minimizing oxidation damage, the SteroScope® Sterilization Technology System incorporates a proprietary gas diffusion technology which creates a pressure differential

in each internal endoscope lumen channel to actively pull hydrogen peroxide vapor from the chamber of the VHP sterilizer through the distal end of each endoscope channel, while the endoscope is in a sterile container. Utilizing a separate mechanism for the rapid diffusion of VHP from the chamber into the individual SteroScope® Sterilization Technology System allows the entire endoscope to be sterilized with less overall peroxide dose exposure.

V. INDICATIONS FOR USE

The SteroScope® Sterilization Technology System is indicated for the terminal sterilization of cleaned reusable Flexible Endoscopes with up to 8 internal lumens with lumen dimensions of:

- ID of 1.0 mm or larger and a length of 3580 mm or shorter and
- ID of 1.2 mm or larger and a length of 4095 mm or shorter

VI. TECHNOLOGICAL CHARACTERISTICS COMPARISON

Table 1 (below) provides a summary of the device's technological characteristics comparing the subject device and the predicate device and reference device(s).

Table 2: TECHNOLOGY Comparison

Characteristic	**Subject Device STEROSCOPE SYSTEM (K233762)**	**Predicate Device STERRAD100NX DUO (K111377)**	**Reference Device STERRAD 100NX EXPRESS (K092622)**	**Comments**
Intend Use	SteroScope Sterilizer is intended for the terminal sterilization of properly prepared (cleaned, rinsed, and dried) flexible endoscopes in Healthcare Facilities. The preprogrammed sterilization cycle operates at low pressure and temperature, suitable for processing endoscopes without leaving toxic residues.	The STERRAD Sterilizers are designed for sterilization of both metal and nonmetal medical devices at low temperatures. Because the cycle operates within a dry environment and at low temperatures, it is especially suitable for instruments sensitive to heat and moisture.	The STERRAD Sterilizers are designed for sterilization of both metal and nonmetal medical devices at low temperatures. Because the cycle operates within a dry environment and at low temperatures, it is especially suitable for instruments sensitive to heat and moisture.	**SIMILAR Subject to predicate & reference**
Indications for Use	The SteroScope Sterilization System is indicated for the terminal sterilization of cleaned reusable flexible endoscopes with up to 8 internal lumens with lumen dimensions of:	The STERRAD® 100NX™ DUO Cycle is an additional optional cycle designed for sterilization of medical devices including most flexible endoscopes, with up to 1 internal lumen with lumen dimension of: 1.0 mm or larger and a length of 875mm or shorter	The STERRAD® 100NX™ EXPRESS Cycle is an additional optional cycle designed for surface sterilization of both metal and nonmetal medical devices at low temperatures. It can sterilize instrument surfaces and it can sterilize rigid and semi-rigid endoscopes without lumens	**SIMILAR Subject to predicate & reference**

Characteristic	Subject Device STEROSCOPE SYSTEM (K233762)	Predicate Device STERRAD100NX DUO (K111377)	Reference Device STERRAD 100NX EXPRESS (K092622)	Comments
	ID of 1.0 mm or larger and a length of 3580 mm or shorter and ID of 1.2 mm or larger and a length of 4095 mm or shorter			
Sterilization Technology	VHP Gas Plasma	VHP Gas Plasma	VHP Gas Plasma	**SAME**
Sterilant	59% H2O2	59% H2O2	59% H2O2	**SAME**
H2O2/cycle	5.8 mL	3.1 mL	10.8 mL	**SIMILAR Subject to predicate & reference**
Chamber Temperature	57° C	57° C	57° C	**SAME**
Chamber Volume	91.0 Liters	93.4 Liters	93.4 Liters	**SIMILAR Subject to predicate & reference**
Load Type	(1) flexible endoscope (8) internal lumens (1.0mm ID x 3585mm)	(2) flexible endoscopes (1) internal lumen (1.0mm ID x 850mm)	(2) Semi-rigid/rigid endoscopes (no lumens up to 500mm)	**SIMILAR Subject to predicate**
Load Weight	17.8 lbs.	13.2 lbs.	10.7 lbs.	**SIMILAR Subject to predicate**
H2O2 Delivery	Extracted from H2O2 consumable and metered	Extracted from H2O2 consumable and metered	Extracted from H2O2 consumable with no metering	**SAME**
Cycle Time	43 mins.	51 mins.	26 mins	**SIMILAR Subject to predicate**

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Table 3 (below) provides a summary of the non-clinical performance testing conducted on the subject device, SteroScope Sterilization System, to establish safety and efficacy. Table 4 below provides a list of standards used in the testing of the SteroScope Sterilization System

Table 3:

Testing Method	Purpose	Acceptance Criteria	Results
System Environmental Testing	System environmental testing under extreme conditions operating conditions	Internal Specification	Pass
SteroScope H_2O_2 Emissions Test	H_2O_2 emissions compliance to required OSHA safety levels	OSHA H_2O_2 SEL/PEL	Pass

Testing Method	Purpose	Acceptance Criteria	Results
System H_2O_2 Concentration Mapping	Peroxide concentration mapping during operation	Internal Specification	Pass
System Temperature Mapping	Temperature mapping during operation	Internal Specification	Pass
System Functional Test	Testing of system functional requirements to ensure conformance to system specifications	Internal Specification	Pass
SteroScope System Shipping	System shipping test for vibration, shock & drop to ensure system and packaging integrity	ISTA 2B	Pass
SteroScope Consumable Shipping	Consumable shipping test for vibration, shock & drop to ensure consumable and packaging integrity	ISTA 2A	Pass
EMC & Electrical Safety	The sterilizer was tested in accordance with IEC 60601-1-2 and IEC 61010-1 standards	IEC 60601-1-2 and IEC 61010-1	Pass
Qualification of Pressure Limits	Validation of sterilizer operational pressure limits	Internal Specification	Pass
Human Factors	Validation of system ergonomics and human factors with clinical users	Internal Specification	Pass
Software Validation	Software verification and validation of software requirements	Internal Specification	Pass
Subsystem Design Verifications	Testing of each subsystem to ensure functional performance met design requirements	Internal Specification	Pass
H2O2 Consumable Shelf-life	Long term stability study of H2O2 consumable to establish shelf life	Internal Specification	Pass
H2O2 Consumable Storage	Stability testing of H2O2 consumable in extreme conditions	Internal Specification	Pass
Endoscope Temperature Mapping	Mapping of endoscope temperatures during cycle to verify the internal and external temperatures of a flexible endoscope	Internal Specification	Pass
Final Process Qualification	Operational process qualification with multiple systems	Internal Specification	Pass
Mated Surface Connector-Port	Half cycle connector efficacy test	No growth of Geobacillus stearothermophilus	Pass
BI & CI Functionality	BI & CI functionality under worst case conditions	No Growth in BI & color change in CI	Pass
AOAC Sporicidal Test	Process and sterilant efficacy for multiple organisms	AOAC Official Method 966.04	Pass
Mated Surface Sterilization	Half cycle mated material efficacy using material coupons	No growth of Geobacillus stearothermophilus	Pass

Testing Method	Purpose	Acceptance Criteria	Results
Material Surface Sterilization	Half cycle surface efficacy using material coupons	No growth of Geobacillus stearothermophilus	Pass
Uniformity Microbial Inactivation	Dosing study to assess uniformity of microbial inactivation	Uniformity in inactivation kinetics based on SLR	Pass
Endoscope Dose Response Curves	Dosing study with various flexible endoscopes	Internal Specification	Pass
Material Bacteriostasis Validation	Confirmation that there are no bacteriostatic effects that inhibit growth for material coupons	No bacteriostatic effect after sterilization with growth of defined micro-organisms	Pass
Bacteriostasis & Fungistasis Validation	Confirmation that there are no bacteriostatic effects that inhibit growth for flexible endoscopes	No bacteriostatic effect after sterilization with growth of defined micro-organisms	Pass
Simulated Use Testing	Worst-case testing with unwashed flexible endoscopes inoculated with test culture challenge	6-log reduction in Geobacillus stearothermophilus	Pass
In-Use Testing	Worst-case testing with clinically used flexible endoscopes.	No growth upon recovery after sterilization	Pass
Functionality & Material Compatibility	Worst-case material compatibility testing of multiple flexible endoscopes with back to back cycles	Internal Specification	Pass
Biocompatibility Coupons	Worst-case residual and cytotoxicity (MTT) testing with material coupons	ISO 10993-5	Pass
Biocompatibility Flexible Endoscopes	Worst-case residual and cytotoxicity (MTT) testing with flexible endoscopes	ISO 10993-5	Pass

Table 4 Standards Used:

Organization	Designation	Title
IEC	60601-1-2 Edition 4.0 2014-02	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC	61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION	Safety requirements for electrical equipment for measurement control and laboratory use - Part 1: General requirements [Including: Corrigendum 1 (2019)]
AAMI	TIR 12:2020	Design, Testing and Labeling of Reusable Medical Devices
ANSI AAMI ISO	11737-1:2018	Microbial Methods Determination of the population of microorganisms
ASTM	E1837-96 (2014)	Simulated Use Test
AAMI ANSI	ST77:2013(R)2018	Containment Devices
ANSI AAMI ISO	17664:2017	Info To Be Provided for the processing of medical devices
AAMI	TIR39:2009(R)2017	Selecting a Microbial Challenge and Inoculation sites
ANSI AAMI ISO	11138-1:2017	BIs part 1
ISO	10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO	10993-12 Fourth edition 2012-07-01	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
USP-NF	1035	BIs for Sterilization
AOAC	966.04	Sporicidal Activity of Disinfectants
AAMI ANSI	ST14:2008	EtO Sterilization in Health Care Facilities
IEC	61000	Electromagnetic Compatibility
ISTA	2A and 2B	International Safe Transit Association
OSHA	CAS 7722-84-1	H2O2 Handling Guidance
AOAC	Official Method 966.04	Sporicidal Activity of Disinfectants. Official Methods of Analysis of the AOAC, 2013 Edition

Conclusion

The conclusion drawn from the non-clinical testing demonstrates that the subject device, SteroScope® Sterilization Technology System submitted under K233762, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K131407, the STERRAD 100NX DUO Cycle, and the legally marketed reference device cleared under K092622, the STERRAD 100NX EXPRESS Cycle.