March 5, 2026

Nanosonics Limited
Nancy Kaiser
Regulatory Affairs Manager
7-11 Talavera Road
Macquarie Park, NSW 2113
Australia

Re: K253267
Trade/Device Name: CORIS System
Regulation Number: 21 CFR 880.6994
Regulation Name: Automated endoscope channel cleaner
Regulatory Class: Class II
Product Code: SEW
Dated: September 29, 2025
Received: January 30, 2026

Dear Nancy Kaiser:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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,

Dolly Singh

Digitally signed by Dolly Singh

For Katharine Segars
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.

510(k) Number *(if known)*
K253267

Device Name
CORIS System

Indications for Use *(Describe)*

The Nanosonics CORIS System is indicated for cleaning of the channels of compatible endoscopes.
The CORIS System is suitable for use in healthcare facilities by trained healthcare personnel.

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 – CORIS System

I. DATE PREPARED

March 4, 2026

II. 510(k) NUMBER

K253267

III. 510(k) SUBMITTER

Nanosonics Limited
7-11 Talavera Road
Macquarie Park NSW 2113
Australia

Contact Person: Nancy Kaiser,
Regulatory Affairs Manager
Address: 7-11 Talavera Road
Macquarie Park, NSW 2113
Australia
Email: n.kaiser@nanosonics.com
Telephone: (317) 854-7625

IV. DEVICE

Trade Name of Device:	CORIS System
Common or Usual Name:	Automated Endoscope Channel Cleaner
Classification:	II
Regulation Number:	21 CFR 880.6994
Product Code:	SEW

V. PREDICATE DEVICE

Predicate Device

Trade Name:	CORIS System
De Novo Classification Number:	DEN240018
Company Name:	Nanosonics Ltd.

VI. DEVICE DESCRIPTION

The CORIS System is an automated electromechanical device which utilizes the CORIS QUANTUM Cleaning Agent to clean endoscope channels (including interior of the lumens, ports, and cylinders) of validated and compatible reusable flexible endoscopes. The CORIS QUANTUM Cleaning Agent is provided as a dry powder, which upon installation is hydrated to create a slurry. During the cleaning cycle, the CORIS System delivers the cleaning agent providing physical cleaning to all endoscope channels. The endoscope channels are then rinsed and purged with air. The CORIS System is intended for over-the-counter use by healthcare personnel.

VII. INDICATIONS FOR USE

The Nanosonics CORIS System is indicated for cleaning of the channels of compatible endoscopes.
The CORIS System is suitable for use in healthcare facilities by trained healthcare personnel.

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The CORIS System with proposed modifications is as safe and effective in terms of technological characteristics and principles of operation to the predicate device, CORIS System.

The subject device, CORIS System shares the same fundamental technological characteristics as the predicate device. Both devices are automated endoscope channel cleaners that utilize the CORIS QUANTUM Cleaning Agent to clean the lumen of the endoscope. The cleaning process relies on physical friction generated as the Cleaning Agent particles pass through both the small and large channels of the endoscope. The Cleaning Agent is delivered in shots, and as the particles move through the channels, the physical action of friction between the particles and the inner surface of the lumen effectively removes soils from the endoscope.

The design, materials and mode of operation are substantially equivalent to the predicate device, with no significant differences that raise new question of safety or effectiveness. Any differences between the subject device and the predicate device have been evaluated through successful verification and validation testing using parameters equivalent as those applied to the predicate device. These evaluations confirm that the differences do not raise new questions of safety or effectiveness.

Table 1. A Comparison between the Subject and Predicate Device

Feature	Subject Device: CORIS System	Predicate Device: CORIS System (DEN240018)	Comparison
Manufacturer	Nanosonics Limited	Nanosonics Limited	Same
Regulation Number	21 CFR 880.6994	21 CFR 880.6994	Same
Product Code	SEW	SEW	Same
Intended Use	The Nanosonics CORIS System is intended to clean the channels of endoscopes, when used in accordance with its labelling. The CORIS System is an electromechanical system that replaces manual cleaning of endoscope channels with an automated, verified and traceable cleaning process. Manual cleaning of endoscope channels is not required prior to cleaning with the CORIS System.	The Nanosonics CORIS System is intended to clean the channels of endoscopes, when used in accordance with its labelling. The CORIS System is an electromechanical system that replaces manual cleaning of endoscope channels with an automated, verified and traceable cleaning process. Manual cleaning of endoscope channels is not required prior to cleaning with the CORIS System.	Same
Indication for Use	The Nanosonics CORIS System is indicated for cleaning of the channels of compatible endoscopes. The CORIS System is suitable for use in healthcare facilities by trained healthcare personnel.	The Nanosonics CORIS System is indicated for cleaning of the channels of the Olympus EVIS EXERA III CF-HQ190L colonovideoscope. The CORIS System is suitable for use in healthcare facilities by trained healthcare workers.	Substantially Equivalent based on V&V testing. .
Operating Principle	Software controlled system that uses the CORIS QUANTUM Cleaning Agent to clean the lumen of the endoscope through physical friction created as the cleaning agent particles pass through the small and large channels of the endoscope. The shots of Cleaning Agent travel through the channels and the physical action created through friction of these particles and the inner surface of the lumen, is what removes soil from the endoscope.	Software controlled system that uses the CORIS QUANTUM Cleaning Agent to clean the lumen of the endoscope through physical friction created as the cleaning agent particles pass through the small and large channels of the endoscope. The shots of Cleaning Agent travel through the channels and the physical action created through friction of these particles and the inner surface of the lumen, is what removes soil from the endoscope.	Same
Cleaning Agent	CORIS QUANTUM	CORIS QUANTUM	Same
Cleaning Agent Open Bottle Shelf Life	5 days	1day	Substantially Equivalent based on V&V testing
Cleaning Agent Shelf Life	7 months	6 months	Substantially Equivalent

			based on V&V testing
Device Performance Standards	IEC 62366 -1 ISO 10993-1 ISO 14971 IEC 60601-4-2:2024 ISO 10993-1 ISO 14971 IEC 60601-1-2 Edition 4.1 2020-09 Consolidated Version IEC 61010-1 Edition 3.1 2017-01 Consolidated Version IEC 61010-2-040:2020 IEC 62304:2006+AMD1:2015 ISO 27001:2002 ANSI/AAMI SW96:2023 AAMI/ANSI/IEC TIR 80001-2-2:2012	ISO 62366 -1 and -2 ISO 10993-1 ISO 14971 IEC 60601-4-2:2024 ISO 10993-1 ISO 14971 IEC 60601-1-2 Edition 4.1 2020-09 Consolidated Version IEC 61010-1 Edition 3.1 2017-01 Consolidated Version IEC 61010-2-040:2020 IEC 62304:2006+AMD1:2015 ISO 27001:2002 ANSI/AAMI SW96:2023 AAMI/ANSI/IEC TIR 80001-2-2:2012	Same
Cleaning Agent Residue Testing	Meets the recommendations FDA Guidance "Medical Washers and Medical Washer-Disinfectors - Class II Special Controls Guidance Document for the Medical Device Industry and FDA Review Staff" February 7, 2002 , FDA Guidance "Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities" August 1993 and FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" March 17, 2015	Meets the recommendations FDA Guidance "Medical Washers and Medical Washer-Disinfectors - Class II Special Controls Guidance Document for the Medical Device Industry and FDA Review Staff" February 7, 2002 , FDA Guidance "Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities" August 1993 and FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" March 17, 2015	Same
Touch Screen	Color touch screen panel	Color touch screen panel	Same
Software/Firmware Control	Yes	Yes	Same
Contains Self-Disinfection Cycle	Yes	Yes	Same
Traceability	An integrated RFID module allowing automated traceability features in the device. Patient information is not received or recorded by the device; therefore, it cannot	An integrated RFID module allowing automated traceability features in the device. Patient information is not received or recorded by the	Same

	be accessed via RFID.	device; therefore, it cannot be accessed via RFID.	
Communication Ports	3 USB ports for connecting external devices 1 Ethernet port The CORIS Device supports external network connection through the integrated Ethernet port.	3 USB ports to connect to external devices 1 Ethernet port The CORIS Device supports external network connection through the integrated Ethernet port.	Same
Key Accessories	CORIS QUANTUM CORIS Adaptor CORIS Smart Drain CORIS Smart Drain Adaptor CORIS Smart Drain Seal CORIS Maintenance Kit Flushing Accessory	CORIS QUANTUM CORIS Adaptor CORIS Splash Guard CORIS Splash Guard Tube CORIS Splash Guard Seal CORIS Self-Disinfection Kit CORIS Lens Cover and Lens Cover Aid	Substantially Equivalent based on V&V testing
Self-Disinfection Disinfectant	Steris Revital-Ox Resert High Level Disinfectant	Steris Revital-Ox Resert High Level Disinfectant	Same

IX. SUMMARY OF NON-CLINICAL TESTING

In support of the substantial equivalence determination, the following non-clinical tests were performed:

Table 2. Summary of Non-clinical Testing

Test	Brief Description	Applicable Standard	Acceptance Criteria	Results (Pass/Fail)
System Life Testing and Endoscope Compatibility	Back-to-back Cleaning and Self Disinfection cycles to assess CORIS System lifetime.	N/A	CORIS System Function - At the end of test, the CORIS device shall still be fit for its intended purpose. Endoscope Function - At the end of the test, the endoscope under test shall still be fit for its intended purpose Installation Accessories Function (Wall Mount, Surface Mount, PSU Bracket) - At the end of the test, the installation accessory under test should show no signs of corrosion or rusting, bending and/or distortion. Multi-dose Cleaning Consumable Capacity - For all completed	Pass

			bottle, CORIS Cleaning Consumable should last for at least the minimum required number of cycles	
CORIS Cleaning Validation - Simulated Use Test	Simulated use testing was conducted under worst case conditions per the FDA Guidance "Medical Washers and Medical Washer-Disinfectors - Class II Special Controls Guidance Document for the Medical Device Industry and FDA Review Staff" February 7, 2002 and "Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities" August 1993 and FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" March 17, 2015	ANSI/AAMI ST98:2022 (Same test methods and acceptance criteria as DEN240018)	Meets standard and recommendations of Section II.I.3.c of FDA Guidance "Medical Washers and Medical Washer-Disinfectors - Class II Special Controls Guidance Document for the Medical Device Industry and FDA Review Staff" February 7, 2002	Pass
Error Handling	The test was to verify the CORIS System's ability to detect error conditions.	N/A	All expected results shall be met.	Pass
User Interface	The test was conducted to verify that the CORIS System appropriately generates and sends notifications to the user regarding errors and other critical process events.	N/A	All expected results shall be met.	Pass
Transportation - CORIS Chassis/Body	Simulated transportation testing performed to ensure that packaging and device will not be compromised during shipping.	ASTM D4169-22	Meets standard	Pass
Transportation - CORIS Engine	Simulated transportation testing performed to ensure that packaging and device will not be compromised during shipping.	ASTM D4169-22	Meets standard.	Pass
Transportation – QUANTUM Cleaning Agent	Simulated transportation testing performed to ensure that packaging and device will not be	ASTM D4169-22	Meets standard	Pass

	compromised during shipping.			
Transportation - CORIS Accessories	Simulated transportation testing performed to ensure that packaging and device will not be compromised during shipping.	ASTM D4169-22	Meets standard	Pass
Chemistry - CORIS Quantum Open Shelf-life	The test was to assess product stability after the cleaning agent container is opened	Q1A(R2) Stability Testing of New Drug Substances and Products	Meets the recommendations of Q1A(R2) Stability Testing of New Drug Substances and Products	Pass
Chemistry - QUANTUM Analysis in an Endoscope After CORIS Cleaning	The test was to evaluate the chemical residues remaining in an endoscope following cleaning with the CORIS System.	N/A (Same test methods and acceptance criteria as DEN240018)	Meets the recommendations of Section II.I.3.e of "Medical Washers and Medical Washer-Disinfectors - Class II Special Controls Guidance Document for the Medical Device Industry and FDA Review Staff" February 7, 2002 and Section II.G.2.c.(3) of "Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities" August 1993 and Section II.C. Criterion 5.F, and Section VI of "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" March 17, 2015	Pass
Materials Compatibility for CORIS System	The test was to evaluate the compatibility of the applicable CORIS device parts and its accessories with self-disinfection agents and wipe chemistries.	ASTM F1980-21 ASTM D543-21	Meets standards and recommendations of Section II.F.3 of "Medical Washers and Medical Washer-Disinfectors - Class II Special Controls Guidance Document for the Medical Device Industry and FDA Review Staff" February 7, 2002 and Section II.C.3 of "Guidance on Premarket Notification [510(k)] Submissions for Automated	Pass

			Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities" August 1993	
CORIS Exterior Device Reprocessing	Test was performed per FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" March 17, 2015	ISO 17664-2:2021 ANSI/AAMI ST98:2022 ASTM E2362-22 ASTM E1837-96 AAMI TIR12:2020 (Same test methods and acceptance criteria as DEN240018)	Meets standards.	Pass
Smart Drain Reprocessing	Test was performed per FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" March 17, 2015	ISO 17664-2:2021 ANSI/AAMI ST98:2022 ASTM E2362-22 ASTM E1837-96 AAMI TIR12:2020 (Same test methods and acceptance criteria as DEN240018)	Meets standards.	Pass
Adaptor Reprocessing	The test was conducted per FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" March 17, 2015 and FDA Guidance "Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/ High Level Disinfectants" January 3, 2000	ISO 17664-2:2021 ANSI/AAMI ST98:2022 ASTM E2362-22 ASTM E1837-96 AOAC 965.12 AAMI TIR12:2020 (Same test methods and acceptance criteria as DEN240018)	Meets standards and the recommendations of Section III.H.5.b of Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants" January 3, 2000	Pass
Smart Drain Adaptor Reprocessing	The test was conducted per FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" March 17, 2015 and FDA Guidance "Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/ High Level Disinfectants" January 3, 2000	ISO 17664-2:2021 ANSI/AAMI ST98:2022 ASTM E2362-22 ASTM E1837-96 AOAC 965.12 AAMI TIR12:2020 (Same test methods and acceptance criteria as DEN240018)	Meets standards and the recommendations of Section III.H.5.b of Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants" January 3, 2000	Pass
Maintenance Kit Reprocessing	The test was conducted per FDA Guidance "Reprocessing Medical Devices in Health Care	ISO 17664-2:2021 ANSI/AAMI ST98:2022 ASTM E2362-22 ASTM E1837-96	Meets standards and the recommendations and Section III.H.5.b of Content and Format	Pass

	Settings: Validation Methods and Labeling" March 17, 2015 and FDA Guidance "Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/ High Level Disinfectants" January 3, 2000	AOAC 965.12 AAMI TIR12:2020 (Same test methods and acceptance criteria as DEN240018)	Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants" January 3, 2000	
Flushing Accessory Reprocessing	The test was conducted per FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" March 17, 2015 and FDA Guidance "Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/ High Level Disinfectants" January 3, 2000	ISO 17664-2:2021 ANSI/AAMI ST98:2022 ASTM E2362-22 ASTM E1837-96 AOAC 965.12 AAMI TIR12:2020 (Same test methods and acceptance criteria as DEN240018)	Meets standards and the recommendations per Section III.H.5.b of "Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants" January 3, 2000	Pass
Self-Disinfection Interval	Test was performed per the FDA Guidance "Medical Washers and Medical Washer-Disinfectors - Class II Special Controls Guidance Document for the Medical Device Industry and FDA Review Staff" February 7, 2002	N/A (Same test methods and acceptance criteria as DEN240018)	Meets the recommendations of Section II.I.3.f of "Medical Washers and Medical Washer-Disinfectors - Class II Special Controls Guidance Document for the Medical Device Industry and FDA Review Staff" February 7, 2002	Pass
Self-Disinfection HLD Efficacy	Test was performed per the FDA Guidance "Medical Washers and Medical Washer-Disinfectors - Class II Special Controls Guidance Document for the Medical Device Industry and FDA Review Staff" February 7, 2002 and FDA Guidance "Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/ High Level Disinfectants" January 3, 2000	AAMI TIR12:2020 (Same test methods and acceptance criteria as DEN240018)	Meets the recommendations of Section III.H.5.b of "Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants" January 3, 2000	Pass

Self-Disinfection Use Conditions Test	Test was performed per the FDA Guidance "Medical Washers and Medical Washer-Disinfectors - Class II Special Controls Guidance Document for the Medical Device Industry and FDA Review Staff" February 7, 2002 and FDA Guidance "Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities" August 1993	AAMI TIR12:2020	Meets the recommendations of Section II.I.3.f of "Medical Washers and Medical Washer-Disinfectors - Class II Special Controls Guidance Document for the Medical Device Industry and FDA Review Staff" February 7, 2002 and Section II.G.2.c of "Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities" August 1993	Pass
Impact of Downstream Reprocessing	Test was performed per FDA Guidance "Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/ High Level Disinfectants" January 3, 2000	N/A (Same test methods and acceptance criteria as DEN240018)	Meets the recommendations of Section III.H.5.a of "Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/ High Level Disinfectants" January 3, 2000	Pass
Cleaning Agent Residues for Biocompatibility	The test was performed to evaluate cleaning agent residues remaining on an endoscope after cleaning with the CORIS System.	N/A (Same test methods and acceptance criteria as DEN240018)	Meets the recommendations of Section II.J of "Medical Washers and Medical Washer-Disinfectors - Class II Special Controls Guidance Document for the Medical Device Industry and FDA Review Staff" February 7, 2002 and Section II.I of "Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities" August 1993 and Section VI of "Reprocessing Medical	Pass

			Devices in Health Care Settings: Validation Methods and Labeling" March 17, 2015	
Software and Cybersecurity	The software testing was conducted as per FDA guidance document "Content of Premarket Submissions for Device Software Functions" issued June 14, 2023 Cybersecurity testing was conducted per FDA guidance documents, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" issued June 27, 2025	N/A (Same acceptance criteria as DEN240018)	Meets the recommendations of FDA guidance document "Content of Premarket Submissions for Device Software Functions" issued June 14, 2023 and FDA guidance document "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" issued June 27, 2025	Pass
Electromagnetic Compatibility and Electrical Safety	Electromagnetic Compatibility (EMC) of the CORIS device has been evaluated in accordance with IEC 60601-1-2, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*. Electrical safety testing of the CORIS device was completed in accordance with IEC 61010-1, *Safety requirement for electrical equipment for measurement, control and laboratory use. Part 1: General requirement*s and IEC 61010-2-040, Safety requirements for electrical equipment for measurement, control and laboratory use. Part 2-040: Particular *requirement for sterilizers and washer-disinfectors used to treat medical materials.*	IEC 60601-1-2 IEC 61010-1 IEC 61010-2-040	Meets standards	Pass
Human Factors	Human factors validation testing of the CORIS System was conducted per FDA Guidance " Applying Human Factors			

	and Usability Engineering to Medical Devices" issued February 3, 2016.			

X. CLINICAL TESTING

N/A

XI. CONCLUSION

Based on the intended use, technological characteristics, and conclusions drawn from the non-clinical tests, proposed device is determined to be Substantially Equivalent (SE) to predicate device granted under DEN240018.