DE NOVO CLASSIFICATION REQUEST FOR CORIS SYSTEM

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Automated endoscope channel cleaner. An automated endoscope channel cleaner is a device intended to replace all or a portion of manual cleaning of internal passages and ports of compatible, reusable flexible endoscopes. Cleaning is conducted using an agent that exerts physical force (e.g., friction) on single or multiple channels of compatible endoscopes for removal of soil. This device type is not intended to provide or replace high-level disinfection or sterilization.

NEW REGULATION NUMBER: 21 CFR 880.6994

CLASSIFICATION: Class II

PRODUCT CODE: SEW

BACKGROUND

DEVICE NAME: CORIS System

SUBMISSION NUMBER: DEN240018

DATE DE NOVO RECEIVED: May 1, 2024

SPONSOR INFORMATION:

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

INDICATIONS FOR USE

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.

LIMITATIONS

The Nanosonics CORIS System is intended to be marketed for Over-The-Counter (OTC) use.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

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.

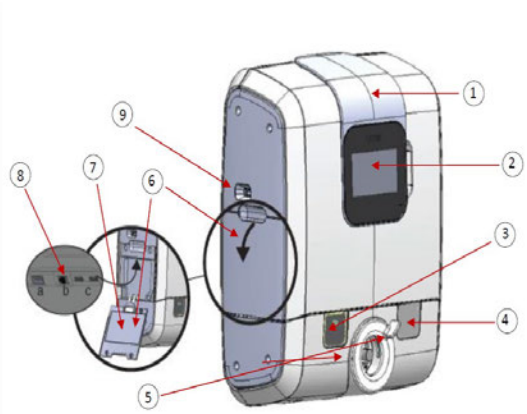
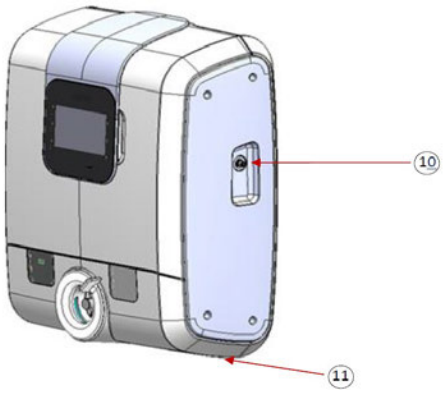
The CORIS System is intended to replace manual cleaning of the channels of Olympus EVIS EXERA III CFHQ190L colonovideoscope (CF-HQ190L) (primary DI number 04953170305115), with an automated cleaning cycle. The CORIS QUANTUM Cleaning Agent is provided as a dry powder, which upon installation is hydrated 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.

All external surfaces of the endoscope must still be cleaned and reprocessed according to the endoscope manufacturer's instructions. An endoscope that has had internal channels cleaned by the CORIS System must be high-level disinfected using an accelerated hydrogen peroxide-based solution, for example, Revital-Ox® RESERT® High Level Disinfectant.

The CORIS System is intended to be used in healthcare settings within reprocessing areas where endoscopes are cleaned, such as endoscope reprocessing departments and central sterile processing departments. The device is intended to be installed and used at the sink in the decontamination area of these departments.

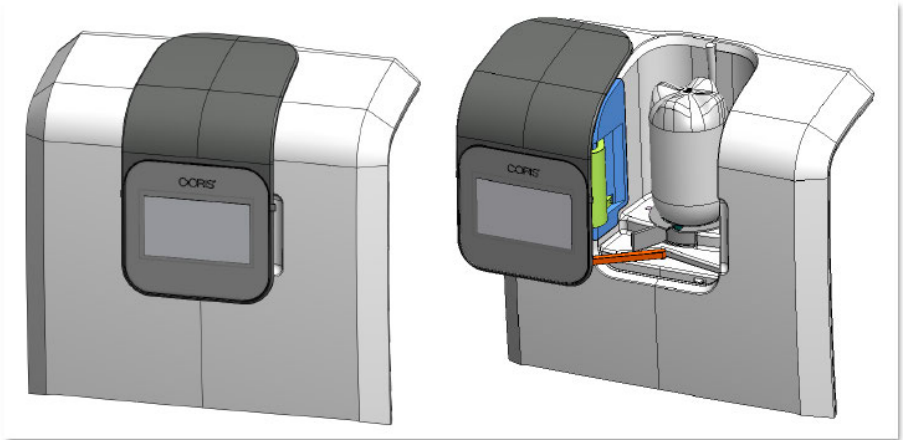
The CORIS System consists of the CORIS Device and its accessories. CORIS accessories are not supplied with the CORIS Device and must be purchased separately, except the following components: 1) CORIS Splash Guard and 2) non-medical device components required during initial set up and installation only including the CORIS Splash Guard Drain Tube, CORIS Drain Spigot Adaptor, Air Supply Tube, Water Supply Tube, Power Supply Unit and Regional Mains Connector, CORIS Splash Guard Mounting Kit, CORIS Lifting Accessory, CORIS Wall Mount Fastening Kit, and CORIS Wall Mount.

CORIS Device

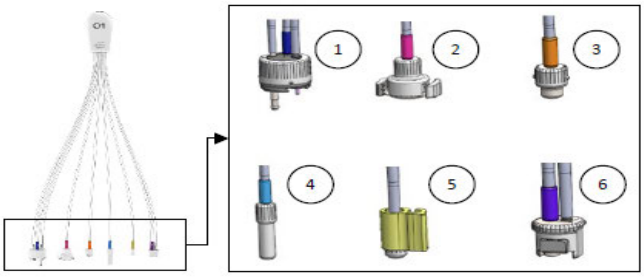
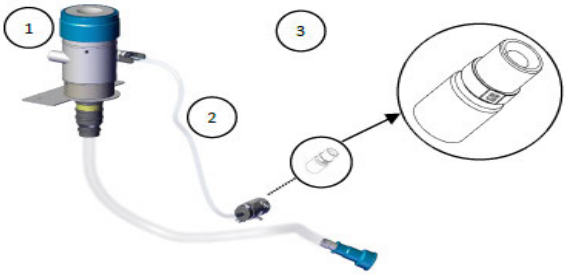
Front and left side	Right side
	

1. Door
2. Touch screen display
3. Barcode reader
4. RFID reader
5. Adaptor port and lock (locked position)
6. Side door (contains the power socket and device label
7. Device label*
8. a. Power socket
   b. Ethernet
   c. 2 x USB ports
9. Power switch
10. Self-Disinfection Input Tube port
11. Location of air, water and drain ports

CORIS Device Door in Closed Position (left) and CORIS QUANTUM Cleaning Agent in Installed Position (right)



CORIS System Accessories

Part Name	Image
CORIS QUANTUM Cleaning Agent	
CORIS O1 Adaptor 1. Suction air/water connector 2. Biopsy connector 3. Auxiliary connector 4. Suction connector 5. Air pipe connector 6. Air/water supply connector	
CORIS Splash Guard 1. CORIS® Splash Guard Body (Reusable) 2. CORIS® Splash Guard Tube (24-hr use) 3. CORIS® Splash Guard Seal (Single use)	
1. CORIS Lens Cover 2. CORIS Lens Cover Aid	

Part Name	Image
CORIS Self-Disinfection Kit 1. CORIS Self-Disinfection Adaptor 2. CORIS Self-Disinfection Input Tube 3. CORIS Self-Disinfection Plug	

SUMMARY OF NONCLINICAL/BENCH STUDIES

REPROCESSING, STERILITY AND SHELF-LIFE

The exterior of the CORIS Device and the CORIS Splash Guard body must be cleaned and disinfected with a Quaternary Ammonium (Quat) wipe after each day or when required in accordance with the CORIS System User Manual.

With the exception of the CORIS QUANTUM Cleaning Agent, the CORIS Device and the associated accessories are provided non-sterile and as such are not labeled with expiration dating (shelf-life). A self-disinfection cycle should be run at least daily; performed according to the CORIS User Manual.

The CORIS QUANTUM Cleaning Agent is labeled with a 6-month shelf life based on data at T - 0 and T - 6-month Real Time. Shelf life testing evaluated the following parameters: moisture content, cleaning agent, performance in CORIS device as a cleaning agent and visual observation of packaging label.

BIOCOMPATIBILITY

The CORIS System biocompatibility risk evaluation was performed by sponsor in accordance with the FDA 2020 Biocompatibility Guidance document, Use of International Standard ISO 10993-1, "*Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*," found at https://www.fda.gov/media/142959/download. The CORIS System has no direct or indirect contact with patient during its intended use. The CORIS User Manual cautions that users should wear appropriate personal protective equipment during operation of the CORIS System.

Additionally, residual testing of the cleaning agent was conducted to assess impact of residual cleaning agent on subsequent reprocessing steps, such as high-level disinfection and sterilization. The sponsor demonstrated that cleaning agent residues do not interfere with subsequent reprocessing steps. Based on the acceptable results of cleaning agent residue analysis, additional biocompatibility testing was not needed and was not performed.

SOFTWARE & CYBERSECURITY

The CORIS device is an automated software controlled electro-mechanical device that houses a touch screen display and Graphical User Interface (GUI) that allows the user to interact with the device. This screen sets and displays the cleaning cycle, cleaning time and cleaning status. The software testing was conducted as per FDA guidance document, "*Content of premarket submissions for Device Software Functions,"* found at *https://www.fda.gov/media/153781/download*.

Cybersecurity testing was conducted per FDA guidance documents, "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"* found at https://www.fda.gov/media/119933/download, and the results were found acceptable.

ELECTROMAGNETIC COMPATIBILITY & ELECTRICAL SAFETY

Electromagnetic Compatibility (EMC) of the CORIS device has been evaluated in accordance with IEC 61326-1, *Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements*, and 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 requirements* 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*. Testing has been successfully completed per the referenced standards, including electrical, mechanical resistance to shock/impact, and mechanical safety testing.

COMPATIBILITY TESTING

The sponsor performed compatibility testing within a lifetime cycle study to evaluate potential damage to the functionality of the endoscope following repeated usage. At the completion of the study, results demonstrated compatibility with the endoscope for (b) (4) cleaning cycles, (b) (4) disinfectant cycle (total of (b) (4) cycle) and (b) (4) cycles for the CORIS adapter.

HUMAN FACTORS TESTING

Summative and supplementary human factors testing were performed (which included two different studies in a simulated use environment) to support the use-safety and effectiveness of use of the CORIS System. The studies evaluated use of the device, and assessed modifications to the device user interface, labeling and training. At the completion of testing, residual risks were demonstrated to be acceptable.

PERFORMANCE TESTING - BENCH

The sponsor conducted the following performance tests to support that the device can achieve its intended use:

- **Cleaning Validation – Simulated Use Testing**
  Simulated use testing was performed in accordance with FDA guidance documentation: "*FDA Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff (February 7, 2002)*", "*FDA Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities (1993)*", and "*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labelling (2015)*" under worst-case simulated use conditions (using Artificial Test Soil 2015 with 20% coagulable blood (cATS) and Combination Test

Soil (CTS) (a mixture of Defibrinated Blood Soil and British Standard Soil at a 9:1 ratio)).

Cleaning validation for the CORIS system assessed colonovideoscopes inoculated with cATS and CTS artificial test soils. Cleaning assessment consisted of quantification of protein and total organic carbon (TOC) using nine endoscope test devices, one negative device control, and one positive device control.

Residual protein and TOC for CORIS cleaned colonovideoscopes were compared to manually cleaned endoscopes for both cATS and CTS. For visual inspection, nine test devices and at least three negative controls were prepared.
Test devices underwent six sequential full simulated use and processing cycles, consisting of soiling of the entire channel surfaces, soil dwelling (1 hour), cleaning with the CORIS system, high level disinfection, flushing with alcohol, and drying. Cleaning efficacy was assessed after a seventh cycle of soiling, soil dwelling, and cleaning with the CORIS system.

At the conclusion of simulated use testing, results met acceptance criteria for residual protein (<3 $\mu g/cm^2$), TOC (<6 $\mu g/cm^2$) and visual inspection (visually clean). The results demonstrated that CORIS System is comparable to or better than manual cleaning based on the acceptance criteria, for all individual channels (suction/biopsy, air/water, and auxiliary channels) of the indicated colonovideoscope.

- **Cleaning Validation – In Use Testing**
  In-use testing was evaluated in accordance with FDA guidance: "*FDA Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff (February 7, 2002)*" and "*FDA Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities (1993)*" and *ISO 15883-1:2009+A1:2014 (Washer-Disinfectors – Part 1: General Requirements, Terms and Definitions and Tests*) to assess CORIS device performance under real-world use conditions.

  EVIS EXERA III CF-HQ190L colonovideoscopes (Olympus) used in a clinical site were employed for the in-use testing. 46 endoscopes were cleaned using the CORIS System covering each channel (suction/biopsy, air/water and auxiliary) and assessment for cleaning markers. The results met acceptance criteria. Additional 46 endoscope replicates were cleaned manually covering each channel (suction/biopsy, air/water, and auxiliary) and evaluated for cleaning markers. Endpoints (protein, TOC and visual inspection) for both endoscope groups were compared. The results demonstrated that the CORIS System performed comparably or better than manual.

- **Cleaning Agent Residues Testing**
  Residual testing was conducted per FDA Guidance: "*FDA Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance*

for the Medical Device Industry and FDA Review Staff (February 7, 2002)", "FDA Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities (1993)" and "*Reprocessing Medical Devices in Health Care Settings Validation Methods and Labeling—Guidance for Industry and Food and Drug Administration Staff (2015)*" and ISO 15883-1:2006 and ISO 15883-5:2021.

Under worst-case conditions, cleaning agent residues remaining in the suction/biopsy channel, air/water channel, auxiliary channel, and distal tip of a CF-HQ190L colonovideoscope after cleaning with the CORIS System were measured 7 times before and after one cleaning cycle and 3 times before and after three back-to-back cleaning cycles. In addition, the sponsor conducted *Mycobacteria* potency testing to assess the impact of cleaning agent residues on the effectiveness of the Revital-Ox Resert high level disinfectant.

The results of cleaning agent residues assessment demonstrated that residual cleaning agent in the channels does not interfere with subsequent high-level disinfection.

- **Self-Disinfection Cycle Validation**
  The CORIS System User Manual recommends that a self-disinfection cycle should be run at least daily. Self-disinfection validation testing was performed under worst-case conditions to demonstrate that high level disinfection of the CORIS system is achieved by the self-disinfection cycle using Revital-Ox Resert HLD solution. The result demonstrated that following self-disinfection, the Colony Forming Unit count of the CORIS device rinse water (seen in the post self- disinfection sample) was not significantly worse than the quality of input utility water.

- **Exterior Cleaning/Disinfection Validation**
  The sponsor performed cleaning and disinfection validation of the CORIS device exterior surface and Splash Guard, which are non-critical equipment surfaces that have no direct or indirect patient contact but will become soiled during use. The validation demonstrated that cleaning and low-level disinfection is suitable for reprocessing of the CORIS device exterior surface and Splash Guard body.

LABELING

The labeling consists of a product label and User Manual.

Labeling for this device is in accordance with the special controls listed below.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of the CORIS System

Risks to Health	Mitigation Measures
Electrical, mechanical or thermal hazards resulting in: • Ineffective cleaning, leading to patient infection • User discomfort or injury	Electromagnetic compatibility testing Electrical, mechanical, and thermal safety testing Software verification, validation, and hazard analysis Labeling
Misuse or use error resulting in patient infection	Human factors/usability testing Labeling
Device failure due to software malfunction and mechanical failure resulting in: • Ineffective cleaning, leading to patient infection • User discomfort or injury	Non-clinical performance testing Software verification, validation, and hazard analysis Cleaning agent shelf-life testing Labeling
Cleaning agent residues impacting further reprocessing, leading to patient infection or adverse tissue reaction	Non-clinical performance testing Biocompatibility evaluation

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the automated endoscope channel cleaner is subject to the following special controls:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including that the device meets all design specifications and performance requirements:

(i) Design verification testing must ensure the device meets its specifications.

(ii) Simulated use testing must evaluate device cleaning efficacy under worst-case simulated use conditions.

(iii) In-use testing must evaluate device performance under clinical use conditions.

(iv) Evaluation of cleaning agent residues must include:
(A) Quantitation of residues in compatible endoscope channels and ports;
(B) Analysis of the impact of device use on subsequent reprocessing steps, such as high-level disinfection and sterilization; and
(C) Evaluation of impact of device use on endoscope biocompatibility.

(v) Compatibility testing of the device with compatible endoscope(s) must be conducted, to include a life cycle assessment study. The labeled life cycle must not exceed the endoscope manufacturer's life cycle specification.

(vi) Cleaning agent shelf-life testing must demonstrate continued performance of the cleaning agent over its labeled shelf life.

(2) Performance testing must demonstrate electromagnetic compatibility and electrical and mechanical safety of the device in the intended use environment.

(3) Software verification, validation, and hazard analysis must be performed for any software components of the device.

(4) Human factors testing must demonstrate that an intended user can correctly use the device for its intended use, based solely on its labeling and instructions for use.

(5) Labeling must include the following:
(i) A detailed summary of the device technical parameters, including any specifications;

(ii) A statement regarding user adherence to the endoscope manufacturer's recommendations for use and cleaning of external/incompatible surfaces, as well as adherence to the manufacturer's validated microbicidal process for the entire device, drying and storage conditions; and

(iii) Instructions for disinfection and maintenance of the automated endoscope channel cleaner.

BENEFIT-RISK DETERMINATION

Benefits

The bench studies performed support that the CORIS System cleans small endoscope channels (that are typically not accessible with brushes) using friction, unlike manual cleaning where liquid detergents are installed through the small channels during cleaning.
The small endoscope channels (air/water and auxiliary channels) are very narrow or geometrically complex by design which makes these channels difficult to clean. Due to the mechanism of action of the cleaning agent (i.e., friction between lumen wall and cleaning agent), the sponsor was able to demonstrate better cleaning of these hard-to-reach endoscope channels compared to the manual cleaning process.

Risks

The identified risks include but are not limited to inadequate cleaning validation which could result in contamination leading to patient infection, cleaning agent interference of subsequent

reprocessing steps (i.e., high-level disinfection or sterilization), device-endoscope incompatibility, deterioration of endoscope channels over time, inappropriate labeling causing use errors, electrical, mechanical and thermal hazards. These risks can be mitigated with appropriate performance bench testing, electromagnetic compatibility testing, software validation/verification and hazard analysis, material compatibility testing, residues analysis, human factors studies, special controls, and labeling.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

> 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.

The probable benefits outweigh the probable risks for the CORIS System. The device provides probable benefits, and the probable risks can be mitigated using general controls and the identified special controls.

CONCLUSION

The De Novo request for the CORIS System is granted and the device is classified as follows:

> Product Code: SEW
> Device Type: Automated endoscope channel cleaner
> Regulation Number: 21 CFR 880.6994
> Class: II