March 19, 2025

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

Re: DEN240018
Trade/Device Name: CORIS System
Regulation Number: 21 CFR 876.1550
Regulation Name: Automated endoscope channel cleaner
Regulatory Class: Class II
Product Code: NTP
Dated: April 30, 2024
Received: May 1, 2024

Dear Nancy Kaiser:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the CORIS System, an over-the-counter device under 21 CFR Part 801 Subpart C with the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the CORIS System, and substantially equivalent devices of this generic type, into Class II under the generic name automated endoscope channel cleaner.

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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On May 1, 2024, FDA received your De Novo requesting classification of the CORIS System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the CORIS System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the CORIS System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

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

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.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the automated endoscope channel cleaner they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 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.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Obinna Echeozo at 240-402-9512.

Sincerely,

BLETA VUNIQI -S

Digitally signed by BLETA VUNIQI -S
Date: 2025.03.19 16:08:42 -04'00'

For,

Binita Ashar, M.D., M.B.A., F.A.C.S.
Director
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health