June 17, 2022

Zuno Medical, Inc.
% Michael Nilo
President and Principal Consultant
Nilo Medical Consulting Group, LLC
3491 Denny Street
Pittsburgh, Pennsylvania 15201

Re: DEN210004
Trade/Device Name: Zuno Smart Sterilization Container
Regulation Number: 21 CFR 880.6855
Regulation Name: Rigid sterilization container with electronic monitoring
Regulatory Class: Class II
Product Code: QJT
Dated: February 11, 2021
Received: February 16, 2021

Dear Michael Nilo:

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 Zuno Smart Sterilization Container, an over-the-counter device under 21 CFR Part 801 Subpart C] with the following indications for use:

> The Zuno Smart Sterilization Container is a reusable sterilization container intended to be used to enclose another medical device that is to be sterilized by a healthcare provider with pre-vacuum, steam sterilization cycles, to maintain sterility after removal from the sterilizer until used, and to monitor and inform users of the status of the container's sterile barrier integrity.
>
> The Zuno Smart Sterilization Container has been validated to allow for the sterilization of its contents in pre-vacuum steam sterilizers with the following parameters: 132 ℃ sterilization temperature, 4-minute sterilization, 30-minute dry time.
>
> Do not use with instruments containing lumens with an inner diameter smaller than 1.2mm and an overall length longer than 500mm. Do not exceed a total container weight of 25lbs.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Zuno Smart Sterilization Container, and substantially equivalent devices of this generic type, into Class II under the generic name rigid sterilization container with electronic monitoring.

FDA identifies this generic type of device as:

Rigid sterilization container with electronic monitoring. A rigid sterilization container with electronic monitoring is a device intended to be used to enclose medical devices that are to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical devices and maintain sterility of the enclosed devices until used. The device provides sterility status of the enclosed medical devices via real time electronic monitoring.

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 February 16, 2021, FDA received your De Novo requesting classification of the Zuno Smart Sterilization Container. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Zuno Smart Sterilization Container 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 Zuno Smart Sterilization Container 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:

Identified Risks to Health	**Mitigation Measures**
Infection resulting from exposure to unsterile instruments due to device failure or failure to properly interpret sterile barrier status	Sterilization validation; Software verification, validation, and hazard analysis; Reprocessing validation; Non-clinical performance testing; Labeling; Human factors testing
Delayed or cancelled treatment due to device failure	Non-clinical performance testing
Adverse tissue reaction	Biocompatibility evaluation
Electric shock to user	Electrical safety testing, Electromagnetic compatibility (EMC) testing, and Labeling

In combination with the general controls of the FD&C Act, the rigid sterilization container with electronic monitoring 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. The following performance characteristics must be evaluated to ensure device function and integrity during challenging use:
  (i) Vent-to-volume testing must demonstrate adequate sterilant penetration.
  (ii) Sterilization validation must demonstrate that the contents to be sterilized can adequately achieve the proposed Sterility Assurance Level (SAL).
  (iii) Performance testing must demonstrate the device accurately informs the end-user of the sterile status of the contents.
  (iv) Performance testing must demonstrate the device can maintain sterility of the enclosed medical products for a minimum 30 day storage period.
  (v) Battery performance and shelf life testing must demonstrate the device maintains its function throughout its total use-life.
  (vi) Battery performance and shelf life testing must demonstrate the device maintains its function during storage, throughout a minimum 30 day sterile storage period.
  (vii) Moisture/sterilant ingress testing must support that the electronic components are adequately sealed and do not allow moisture/sterilant ingress.
  (viii) Microbial barrier testing must support that the seals, gaskets, valves, etc. provide an adequate barrier to microbial ingress.
  (ix) Seal integrity testing must demonstrate that an adequate seal is created and maintained throughout the sterile storage period.
  (x) Mechanical functionality testing must demonstrate proper function of any valves, gaskets, or other components essential to the function of the device.
  (xi) For devices with handles, handle strength testing must demonstrate the handles can withstand the maximum indicated load weight.
  (xii) Corrosion resistance testing must demonstrate adequate function of any components susceptible to corrosion following the most challenging use.
  (xiii) Dryness evaluation testing must demonstrate the contents to be sterilized are dry prior to storage.
  (xiv) Simulated use testing must evaluate device performance (including maintenance of sterility and accurate sterility status monitoring) under real-world worst-case use conditions.
(2) Device components that may contact medical products must be demonstrated to be biocompatible.
(3) Performance data must validate the reprocessing instructions for the reusable components of the device.
(4) Software verification, validation, and hazard analysis must be performed.
(5) Human factors testing must be performed to demonstrate that end user(s) can safely and correctly use the device, based solely on the directions for use.
(6) Performance data must demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.
(7) Labeling must include:
  (i) Warnings, cautions, and limitations for safe use of the device including:
    (A) A precaution that the lids/trays and any accessories should only be used with the sterilization container.
    (B) A precaution that the use of nonabsorbent tray liners can cause condensate to pool.

(ii) Device operating procedures including:
  (A) Instructions for closures, gaskets, type, sizes, and valve assembly weight as appropriate.
  (B) Instructions for density and distribution of contents, stacking patterns, or any other recommendations pertaining to load configuration of the medical devices to be sterilized.
(iii) A description of the validated length of time sterility can be maintained.
(iv) Identification of any replaceable components, information about the expected life of these components, and instructions for procedures on replacement when needed.
(v) Identification of products intended for sterilization that are compatible for use with the device.
(vi) Description of the required preparation of products intended for sterilization in the device.

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 rigid sterilization container with electronic monitoring 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).

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 Christopher Dugard at 240-402-6031.

Sincerely,

David Krause -S Digitally signed by David Krause -S Date: 2022.06.17 14:37:39 -04'00'

for Binita S. 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