DE NOVO CLASSIFICATION REQUEST FOR ZUNO SMART STERILIZATION CONTAINER

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 880.6855

CLASSIFICATION: Class II

PRODUCT CODE: QJT

BACKGROUND

DEVICE NAME: Zuno Smart Sterilization Container

SUBMISSION NUMBER: DEN210004

DATE DE NOVO RECEIVED: February 16, 2021

SPONSOR INFORMATION:

Zuno Medical, Inc.
743 Camden Ave, Suite B
Campbell, CA 95008

INDICATIONS FOR USE

The Zuno Smart Sterilization Container is indicated as follows:

> 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 °C 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.

LIMITATIONS

This is an over-the-counter device.

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

DEVICE DESCRIPTION

The Zuno Smart Sterilization Container is a reusable, rigid sterilization container intended to enclose surgical instruments during steam sterilization, to allow for sterilization of the enclosed medical devices, maintain sterility of the container contents after removal from the sterilizer until intentionally opened in the surgical setting, and to inform the user of the status of the container's sterile barrier.

The Zuno Smart Sterilization Container has been validated for use in pre-vacuum steam sterilizers with the following parameters: 132°C sterilization temperature, 4-minute sterilization, 30-minute dry time.

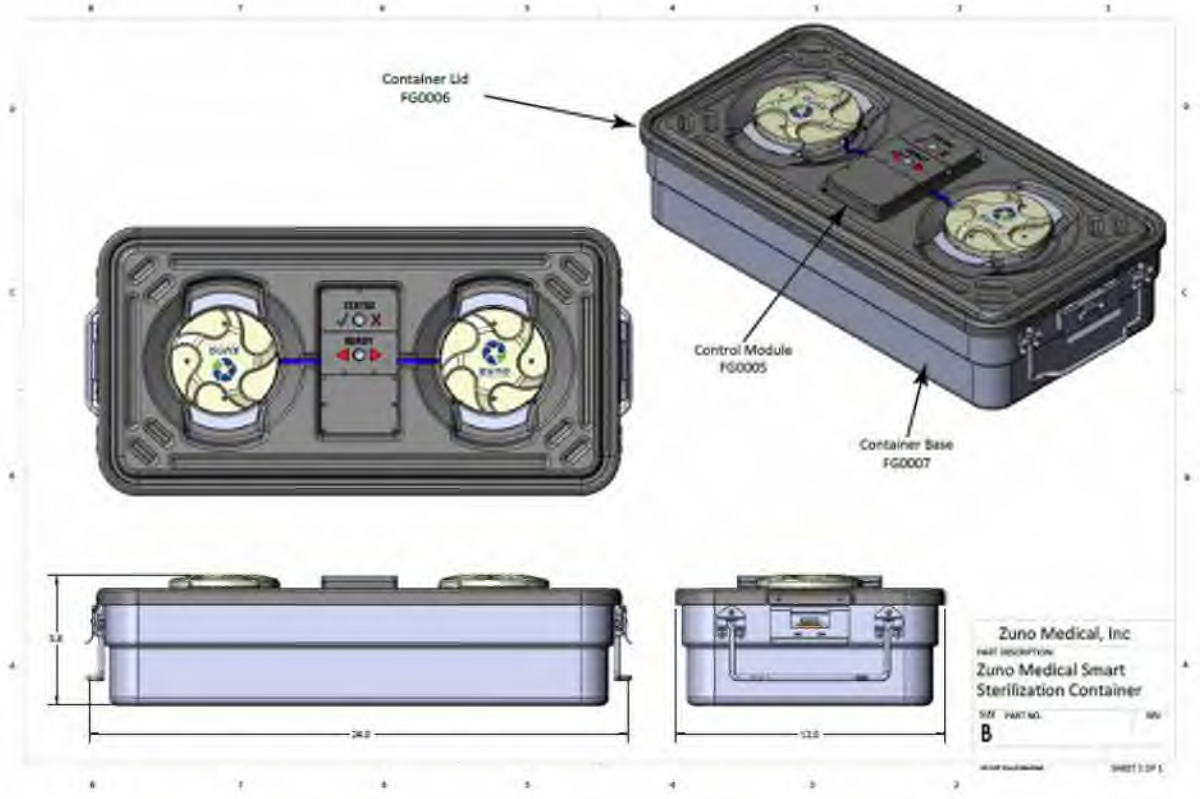
It has been validated for use with instruments containing lumens with an inner diameter smaller than 1.2mm and an overall length longer than 500mm. Do not exceed a total container weight of 25lbs.

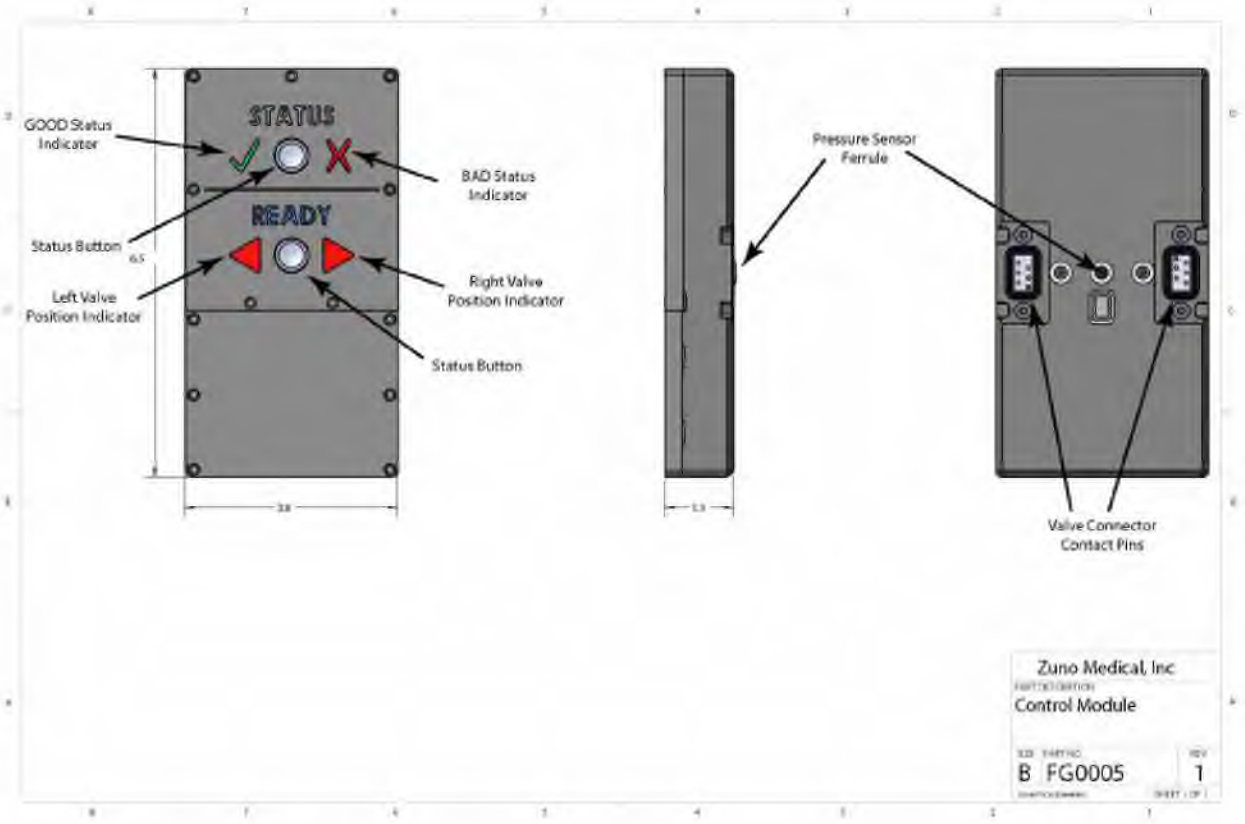
The Zuno Smart Sterilization Container is validated to show that its contents can achieve required sterility levels during typical use. When the user queries the system following a sterilization cycle and prior to opening the container to access its contents, they are checking the integrity of the sterile barrier. This barrier is qualified by three (3) primary factors:

- The valves must have remained open for the entirety of the sterilization cycle,
- The valves must have closed when control module triggers closure guided by data from the pressure sensor during drying phase of the sterilization cycle,
- Following sterilization, the real-time pressure within the container must be below a target threshold to determine whether the sterile barrier has been compromised.

The sensors provide feedback to the microcontroller so that it may identify the stages of the sterilization cycle and close the valves at the appropriate time to achieve the internal sterile environment. The firmware and microcontroller also coordinate with the status button to query the internal state of the container and the indicator lights provide feedback to the user.

The Zuno Smart Sterilization Container will be offered in one size initially, a Full-Size Sterilization Container.





The device is composed of 3 primary components: the lid assembly (which includes the valves and has a space for attaching the control module), the base assembly (which houses the instruments to be sterilized), and the control module (which electronically controls valve actuation and monitors the low-pressure state of the container).

SUMMARY OF BENCH STUDIES

REPROCESSING, STERILITY AND SHELF-LIFE

The Zuno Smart Sterilization Container does not itself need to be sterilized. It is intended to maintain the sterility of the sterilized instruments contained within. Performance related to this aspect was reviewed as a part of the performance testing. The device does include instructions for reprocessing between uses. Specifically, the sponsor has included cleaning instructions that they have validated according to the FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling".

The device is not labeled with a shelf-life; however, the labeling includes instructions describing how the end user is able to determine if the unit is damaged or at the end of its use-life. To support that the device can withstand multiple rounds of sterilization and reprocessing, test articles were exposed to hundreds of worst-case cycles with reprocessing occurring between each cycle.

BIOCOMPATIBILITY

The Zuno Smart Sterilization Container is not meant to contact patients. However, there may be indirect contact as the container contacts the medical devices to be sterilized, which will then have contact with patients. To address this, the sponsor provided cytotoxicity testing following ISO 10993-5:2009, which showed the device to be non-cytotoxic.

SOFTWARE

The software level of concern was considered major since a failure could result in delayed surgical procedures or potential infection. Testing was provided to demonstrate that the device meets all requirements outlined in the FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" for software of major level of concern. The software is intended to monitor environmental conditions within the container and autoclave so the device can register when a drying phase has ended and the valves should close. It also monitors the valve position to ensure they are in the appropriate position. The device is equipped with a Universal Asynchronous Receiver/Transmitter (UART) for diagnostic purposes. Software verification and validation activities were conducted to confirm that the device software met the defined software specifications.

ELECTROMAGNETIC COMPATIBILITY & ELECTRICAL SAFETY

Electromagnetic compatibility (EMC) and Electrical safety (ES) testing were provided. Testing demonstrated that the system was compliant to IEC 60601-1:2005 (Third edition) + CORR 1:2006 + CORR 2:2007 + A1: 2012 and IEC 60601-1-2:2014 (Fourth edition). Emissions testing was provided per CISPR 11:2015, electrostatic discharge testing was provided per IEC 61000-4-2:2008, Radiated RF Electromagnetic Fields testing was provided per IEC 61000-4-3:2010, Magnetic Fields testing was provided per IEC 61000-4-8:2009, Touch Current testing was provided per IEC 60601-1:2012, and Battery Safety testing per IEC 60086-4 + UL1642.

HUMAN FACTORS

A Human Factors study was provided in accordance with the guidance "Applying Human Factors and Usability Engineering to Medical Devices". User and user-interface focused risk analysis combined with an identification of tasks that the two user groups of the device must perform when using the device established a set of critical tasks that provided the foundation for the Human Factors study. The HF/UE validation study collected observational data of subjects fitting into one of two user groups (i.e. sterile processing department staff or operating room staff) performing all of the critical tasks required to clean the device, inspect the device, prepare the device for sterilization, sterilize the device, verify the integrity of the sterile barrier, open the device, and transfer the contents of the container to the sterile field.

PERFORMANCE TESTING – BENCH

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

- Vent-to-volume testing was provided to support adequate sterilant penetration into the container.
- Sterilization validation per ANSI/AAMI ST77:2013 was provided to support that the container allows for the contents to be sterilized to a Sterility Assurance Level (SAL) of 10^{-6}. Thermal mapping was also provided to support device exposure throughout the container.
- Battery performance testing has supported that the battery maintains its function throughout the proposed storage period as well as throughout the device's entire proposed use life. This was done through a combination of bench studies and simulated-use testing.
- Moisture ingress testing for the electronic components was provided to support that no moisture enters the electronic control module under worst case conditions.
- Microbial barrier testing was provided to support that the device does not allow microbial ingress under worst case conditions.
- Seal integrity testing was provided to support that the device maintains an appropriate seal throughout the proposed storage period.
- Mechanical functionality testing was provided to support that the valve/latch assemblies, electro permanent magnet, gaskets, etc. perform as intended.
- Handle strength testing was provided to support that the handles can support the indicated maximum weight of 25lbs.
- Electronic control module testing was provided to support that the control module functions as intended. Specifically, testing was provided supporting the module can accurately inform the end-user of the status of the contents in all situations throughout the entire validated storage period including accurate readouts for the various scenarios the module might be exposed to (including successful cycles, failed cycles, aborted cycles, cycles under sub-optimal conditions, etc.). Performance was supported through a combination of bench studies and simulated-use testing.
- Corrosion resistance testing was provided to support that the risk of corrosion for susceptible components has been mitigated by showing that no corrosion has occurred following worst-case use of the device.
- Dryness evaluation was provided to support the contents to be sterilized are adequately dried and no moisture is present following exposure to the sterilant.
- Simulated use testing was provided by repeatedly exposing the test articles to worst case use conditions followed by worst case (i.e. most intensive) reprocessing. The device was also artificially soiled in the most challenging locations to ensure soil build-up does not impact device functionality.
- In-use testing was addressed via the provided human factors study, discussed above.
- Long term sterile storage assessment was provided to support that the system can maintain sterility and accurately inform the end-user of the status well beyond 30 days of storage. Simulated use was conducted on multiple test articles followed

by long term storage under a variety of conditions. Device functionality was confirmed at multiple timepoints throughout the study.

The device has been appropriately evaluated for performance on the bench.

LABELING

The labeling consists of Instructions for Use and packaging labels. The instructions for use include the indications for use; a description of the device, contraindications, warnings, precautions; information on use-life; and instructions for the safe use of the device.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of a rigid sterilization container with electronic monitoring:

Identified Risks to Health and Mitigation Measures

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

SPECIAL CONTROLS

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.

BENEFIT-RISK DETERMINATION

Benefit

The current paradigm for rigid sterilization containers is that they support, through testing, that the container will allow for the contents to be sterilized to an appropriate Sterility Assurance Level (SAL) and that the container can maintain the sterility of the contents for the duration of the proposed shelf-life. From an end-user perspective, there is no way to determine if the sterile barrier has been compromised other than tamper-evident accessories available with many models. Based on the proposed indications for use, the subject device intends to perform as a typical rigid sterilization container with the added feature of informing the end-user of the status of the sterile barrier. With appropriate testing and controls in place, the probable benefit of this feature is it will add another layer of confidence that devices being stored in these containers will be sterile when used. Proper use of this device is also likely to prevent the delay of treatment as contaminated or not successfully sterilized instruments are often not identified until they are opened when needed. This device will allow the end-user to query the sterile status before the container is transported to the point of use. These probable benefits were supported through both non-clinical performance testing as well as simulated/in-use testing.

Risk

The identified risks have been mitigated with appropriate performance testing focusing on performance of the control module and valves as well as addressing human factors and the unique risks this device poses related to electrical safety and EMC.

Patient Perspectives

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

Benefit/Risk Conclusion

Based on the performance testing provided (in particular sterilization validation, software verification/validation, maintenance of sterility testing, reprocessing validation, and non-clinical testing supporting validation of the monitoring mechanism, labeling, and human factors study) the sponsor has adequately supported that the device will accurately inform the end-user of the sterile status of the contents of the container. This feature will aid in both assuring the end-user the contents are sterile as well as prevent delayed treatment. This testing has also mitigated the probable risk of infection resulting from exposure to unsterile instruments or from an end-users' misinterpretation of the sterility status display. Biocompatibility testing has mitigated the risk of

adverse tissue reaction. Electrical safety/EMC testing and labeling have mitigated the risk of electric shock to the end user.

In conclusion, given the testing provided above, for the following indication statement:

> 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 °C 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.

The probable benefits outweigh the probable risks for the Zuno Smart Sterilization Container. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the Zuno Smart Sterilization Container is granted and the device is classified as follows:

> Product Code: QJT
> Device Type: Rigid sterilization container with electronic monitoring
> Regulation Number: 21 CFR 880.6855
> Class: II