February 11, 2025

Infinitum Eta Ltd.
Avital Barlev
Vice President QA&RA
Hatnufa St. 6
Petach Tikva, 4951024
Israel

Re: K243317
Trade/Device Name: NUVENTUS NV.C™ Surgical Cassette and Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: October 22, 2024
Received: October 22, 2024

Dear Avital Barlev:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.02.11 11:03:44 -05'00'

for: Christopher K. Dugard
Division 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)*
K243317

Device Name
NUVENTUS NV.C™ Surgical Cassette and Tray

Indications for Use *(Describe)*
The NUVENTUS NV.C™ Surgical Cassette and Tray is intended to enclose other medical devices that are to be sterilized by a health care provider. The NUVENTUS NV.C™ Surgical Cassette and Tray is intended to allow sterilization of the enclosed medical devices.
The NUVENTUS NV.C™ Surgical Cassette and Tray requires the use of an FDA cleared wrap to maintain the sterility of the enclosed devices. The NUVENTUS NV.C™ Surgical Cassette and Tray should be enclosed in a sterilization wrap that is FDA cleared for the indicated cycle, and moist heat (steam) sterilized using the following cycle: Pre-vacuum steam: 132°C (270°F) for 4 minutes with 30 minutes drying time.
The NUVENTUS NV.C™ Surgical Cassette and Tray is intended for sterilization of non-porous loads.
The NUVENTUS NV.C™ Surgical Cassette and Tray is recommended not to be stacked during sterilization. The combined weight of the NUVENTUS NV.C™ Surgical Cassette and Tray and the associated instruments is 220 grams. The weight of the empty NUVENTUS NV.C™ Surgical Cassette and Tray is 200 grams.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(K) Summary (K243317) for Infineta's NUVENTUS NV.C™ Surgical Cassette and Tray

**Date Prepared:** 11 February 2025

**1. Submitter**


**Company Name:** Infinitum Eta Ltd
**Address:** Hatnufa St. 6, Petach Tikva, 4951024, Israel
**Phone and E-mail:** avitalb@infinetamed.com; +972-54-2272773
**Contact Person:** Avital Barlev, Vice President QA&RA


**2. Device:**

**Proprietary/Trade Name:** NUVENTUS NV.C™ Surgical Cassette and Tray
**Common Name:** Instrument Sterilization Trays
**Regulation Number:** 21 CFR 880.6850
**Regulation Name:** Containers, Trays, Surgical Cassettes & Other Accessories
**Regulatory Class:** Class II
**Product Code:** KCT

**3. Predicate Device:** Z-Systems AG's ST-Z5, cleared under K201878.

**4. Device Description**

The subject device is a reusable rigid container, comprising a base (bottom), a removable inner tray, and a lid (cover). It is designed to organize and protect NUVENTUS NV.C™ instruments that fall within the cleaning and sterilization validation scope and are sterilized in the tray by a healthcare provider. The base, inner tray, and lid components are designed to be integrated into a single unit which contains and protects the interior contents during sterilization. The tray is perforated to allow for penetration of the sterilant, are to be used with moist heat (steam), and require the use of an FDA cleared wrap to maintain sterility. The subject device components are manufactured from injection molded polyphenylsulfone (PPSU), and holders of various geometries to position instruments in the trays are manufactured from silicone.

**5. Indications for Use**

The NUVENTUS NV.C™ Surgical Cassette and Tray is intended to enclose other medical devices that are to be sterilized by a health care provider. The NUVENTUS NV.C™ Surgical Cassette and Tray is intended to allow sterilization of the enclosed medical devices.

The NUVENTUS NV.C™ Surgical Cassette and Tray requires the use of an FDA cleared wrap to maintain the sterility of the enclosed devices. The NUVENTUS NV.C™ Surgical Cassette and Tray should be enclosed in a sterilization wrap that is FDA cleared for the indicated cycle, and moist heat (steam) sterilized using the following cycle: Pre-vacuum steam: 132°C (270°F) for 4 minutes with 30 minutes drying time.

The NUVENTUS NV.C™ Surgical Cassette and Tray is intended for sterilization of non-porous loads.

The NUVENTUS NV.C™ Surgical Cassette and Tray is recommended not to be stacked during sterilization. The combined weight of the NUVENTUS NV.C™ Surgical Cassette and Tray and the associated instruments is 220 grams. The weight of the empty NUVENTUS NV.C™ Surgical Cassette and Tray is 200 grams.

## 6. Comparison of Technological Characteristics

A tabular comparison of technological characteristics is presented herein:

**Table 1: Indications for Use Comparison**

| Device Name | | Indications for Use |
|---|---|---|
| **Subject Device** | NUVENTUS NV.C™ Surgical Cassette and Tray (K243317) | The NUVENTUS NV.C™ Surgical Cassette and Tray is intended to enclose other medical devices that are to be sterilized by a health care provider. The NUVENTUS NV.C™ Surgical Cassette and Tray is intended to allow sterilization of the enclosed medical devices.<br>The NUVENTUS NV.C™ Surgical Cassette and Tray requires the use of an FDA cleared wrap to maintain the sterility of the enclosed devices. The NUVENTUS NV.C™ Surgical Cassette and Tray should be enclosed in a sterilization wrap that is FDA cleared for the indicated cycle, and moist heat (steam) sterilized using the following cycle: Pre-vacuum steam: 132°C (270°F) for 4 minutes with 30 minutes drying time.<br>The NUVENTUS NV.C™ Surgical Cassette and Tray is intended for sterilization of non-porous loads.<br>The NUVENTUS NV.C™ Surgical Cassette and Tray is recommended not to be stacked during sterilization. The combined weight of the NUVENTUS NV.C™ Surgical Cassette and Tray and the associated instruments is 220 grams. The weight of the empty NUVENTUS NV.C™ Surgical Cassette and Tray is 200 grams. |
| **Primary Predicate Device** | ST-Z5 (K201878) | ST-Z5 surgical trays are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. ST-Z5 surgical trays are intended to allow sterilization of the enclosed medical devices. ST-Z5 surgical trays require the use of an FDA cleared wrap to maintain the sterility of the enclosed devices. The trays are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycle, and moist heat (steam) sterilized using the following cycle: Pre-vacuum steam: 132 °C (270 °F) for 4 minutes with 20 minutes drying time. ST-Z5 surgical trays are intended for sterilization of non-porous loads. ST-Z5 surgical trays are recommended not to be stacked during sterilization. The combined weight of the ST-Z5_c_m_c(t)_m(t) tray and the associated instruments is 441 grams. The weight of the empty ST-Z5_c_m_c(t)_m(t) tray is 361 grams. The combined weight of the Z5-BL/TL tray and the associated instruments is 427 grams. The weight of the empty Z5-BL/TL tray is 363 grams. |

**Table 2: Technological Characteristics Comparison**

| **Feature** | **Subject Device** | **Primary Predicate Device** | **Technological Characteristics Comparison** |
|---|---|---|---|
| | **NUVENTUS NV.C™ Surgical Cassette and Tray (K243317)** | **ST-Z5 (K201878)** | |
| **Product Code** | KCT | KCT | Identical |
| **Design** | Rigid polymer base, lid, and removable inner tray | Rigid polymer base, lid, and removable inner tray | Identical |
| Materials | Polyphenylsulfone [lid, base, tray] | Polyphenylsulfone [lid, base, tray] | Identical |

| Feature | Subject Device | Primary Predicate Device | Technological Characteristics Comparison |
|---|---|---|---|
| | **NUVENTUS NV.C™ Surgical Cassette and Tray (K243317)** | **ST-Z5 (K201878)** | |
| | Medical grade silicone [grommets/holders] | Medical grade silicone [grommets/holders] | |
| Materials compatible with Sterilization Method | Yes | Yes | Identical |
| Perforated | Yes; allows moist heat (steam) penetration to achieve sterilization | Yes; allows moist heat (steam) penetration to achieve sterilization | Identical |
| Number of Overall Sizes | 1 | 1 | Identical |
| Number of Configurations | 1 | 2 | Similar |
| Overall Dimensions | 138L x 98W x 62H [mm] | 185.1L x 133.6W x 61.5H [mm] | Similar |
| Vent to Volume Ratio | 0.0172 cm2 / cm3 | 0.01596 cm2 / cm3 | Similar |
| **Reusable** | Yes | Yes | Identical |
| Number of Uses | 225 | 101 | Similar |
| Use Life Testing | Reusable up to 225 cycles<br>Assembled, cleaned, disinfected and sterilized<br>Visual inspection<br>Defect and deformation<br>Functional performance (Cassette and Tray) | Reusable up to 101 cycles<br>Assembled and sterilized<br>Visual inspection<br>Component dimensional fit verification<br>Functional closure (lid-base latch) verification | Similar |
| **Sterilization Method** | Moist Heat | Moist Heat | Identical |
| **Sterilization Cycles** | Fractionated vacuum (pre-vacuum)<br>Exposure at 132 °C (270 °F) for 4 minutes with 30 minutes drying time | Fractionated vacuum (pre-vacuum)<br>Exposure at 132 °C (270 °F) for 4 minutes with 20 minutes drying time | Similar |
| **Sterile Barrier** | Sterilization wrap, FDA cleared for indicated method and cycle | Sterilization wrap, FDA cleared for indicated method and cycle | Identical |

## 7. Technological Comparison Discussion:

The subject device is similar in indications and design principles to the predicate device.

The subject device and the predicate device have the same intended use, the same product classification and product code (KCT), and have similar Indications for Use statements.

Except for the details concerning the weights of the empty and loaded trays, the indications for use statement for the subject device is identical to that of the predicate device K201878.

The subject device and the predicate device are reusable rigid sterilization trays intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Components of the subject device and the predicate device are perforated to allow for penetration of the sterilant, are to be used with the same moist heat (steam) sterilization cycle and require the use of an FDA-cleared wrap to maintain sterility.

The subject device and the predicate device include components manufactured from polyphenylsulfone (PPSU) and silicone, and both devices are provided in one overall size. While the predicate device is provided in two configurations, the subject device is provided in one configuration. The overall dimensions of the subject device are smaller than the overall dimensions for the predicate device and the vent to volume ratio of the subject device is larger than the vent to volume ratio of the predicate device.

There are minor differences in the configuration, dimensions, sizes, or designs between the subject device and the predicate device. The differences are related to the specific design features and system components and are supported by the cleaning and sterilization validation and use life testing performed.

The subject device and the predicate device have different use life, 225 compared to 101, respectively.

## 8. Non-clinical Testing Summary

Provided below is a summary of the non-clinical performance testing included in this submission, including the test methods, purpose, acceptance criteria, and results.

**Table 3: Non-Clinical Testing Summary**

| Test Methodology | Purpose | Acceptance Criteria | Results |
|---|---|---|---|
| Validation of the Manual Cleaning Process According to the ISO 17664 and the AAMI ST98 Standards | Evaluate and validate the manual cleaning of the subject devices | **Extraction Recovery -** The extraction efficiency for each marker should be no less than 70%. The amounts of each marker residual detected in the fourth extract should be less than 10% of that detected in the first extraction.<br>**Residual marker testing** – Protein Assay Acceptance criterion: less than 6.4 µg/cm$^2$ Assay quantitation limits: 2.5 µg/mL Hemoglobin assay Acceptance criterion: less than 2.2 µg/cm$^2$ Assay quantitation limits: 10.0 µg/mL | Pass |
| Validation of the Automated Cleaning Process According to the ISO 17664 and the AAMI ST98 Standards | Evaluate and validate the automated cleaning of the subject devices | **Extraction Recovery -** The extraction efficiency for each marker should be no less than 70%. The amounts of each marker residual detected in the fourth extract should be less than 10% of that detected in the first extraction.<br>**Residual marker testing** – Protein Assay Acceptance criterion: less than 6.4 µg/cm$^2$ Assay quantitation limits: 2.5 µg/mL Hemoglobin assay Acceptance criterion: less than 2.2 µg/cm$^2$ Assay quantitation limits: 10.0 µg/mL | Pass |
| Sterilization Validation According to the ISO 17664 - ISO 17665 Standards and the AAMI TIR 12 Technical Report | Validate a sterilization cycle and drying time of the subject devices | Acceptance criterion: 3 consecutive half-cycles will demonstrate complete inactivation of all biologic indicators; A minimum SAL of $10^{-6}$ is achieved if the Instructions for Use are followed | Pass |

| Test Methodology | Purpose | Acceptance Criteria | Results |
|---|---|---|---|
| | | Acceptance criterion: Using pre-cycle and post-cycle weights, the weight gain after drying will not exceed +3% | |
| Use Life Testing<br>FDA Guidance<br>*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* and ISO 13402:1995 | Life Cycle (simulated use) testing after 225 cleaning, disinfection and sterilization cycles | Acceptance criteria: Visual inspection, functional verification for 225 use cycles | Pass |
| Biocompatibility of Subject Device (by cytotoxicity testing)<br>ISO 10993-5<br>ISO 10993-12 | The purpose of this test is to evaluate the cytotoxicity potential of the test article using an in vitro cell culture assay. | Acceptance criterion: ≤ 2 reactivity grade after exposure to extract of the device | Pass |

In summary, the nonclinical testing provided for these devices met the acceptance criteria for each standard and test methodology used to evaluate the devices as shown in the table above.

No clinical data were included in this submission.

## 9. Conclusion

To conclude, the conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K201878.