March 25, 2021

Z-Systems AG
% Kevin Thomas
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K201878
Trade/Device Name: St-z5
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: February 25, 2021
Received: February 26, 2021

Dear Kevin Thomas:

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 (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 located 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.

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 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Clarence W. Murray III, Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201878

Device Name

ST-Z5

Indications for Use *(Describe)*

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.

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.

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510(k) Summary

K201878

ST-Z5

Z-Systems AG

March 23, 2021

ADMINISTRATIVE INFORMATION

Manufacturer Name	Z-Systems AG Werkhofstrasse 5 CH-4702 Oensingen Switzerland Telephone +41 62 388 69 69
Official Contact	Rubino DiGirolamo, CEO
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 858-792-1235 Fax +1 858-792-1236 Email kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	ST-Z5
Common Name	Instrument sterilization trays
Regulation Number	21 CFR 880.6850
Regulation Name	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Regulatory Class	Class II
Product Code	KCT
Classification Panel	General Hospital
Reviewing Office	Office of Surgical and Infection Control Devices (OHT4)
Reviewing Division	Division of Infection Control and Plastic Surgery Devices (DHT4B)

PREDICATE DEVICE INFORMATION

The primary predicate device is:

K171713, Neodent Instrument Kits, JJGC Indústria e Comércio de Materiais Dentários S.A.

INDICATIONS FOR USE

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.

SUBJECT DEVICE DESCRIPTION

The subject device trays are reusable rigid containers, comprising a base (bottom), a removable inner tray, and a lid (cover). The subject device trays are to be used to organize and protect the instruments that are sterilized in the trays by the 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 trays are 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. The subject device includes two instrument trays that have the same size (same lid, base, and enclosed volume) and two inner tray configurations.

SUMMARY OF NON-CLINICAL TESTING

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

Summary of Nonclinical Testing

Test Methodology	Purpose	Acceptance Criteria	Results
Automated Cleaning Validation FDA Guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* (issued March 2015)	The purpose of this test is to validate that the cleaning instructions provided in the Instructions for Use appropriately clean the tray, and to ensure the sterilization cycle will be effective.	Protein assay – Micro BCA Protein Assay Acceptance criterion: less than 6.4 µg/cm^2 Assay quantitation limits: 2.0 µg/mL Hemoglobin assay Acceptance criterion: less than 2.2 µg/cm^2 Assay quantitation limits: 10.0 µg/mL	Pass Pass
Sterilization Validation including sterilant penetration and dry time validation ANSI/AAMI/ISO 17665-1 ANSI/AAMI/ISO 17665-2	The purpose of this test is to validate that the sterilization instructions listed in the Instructions for Use appropriately sterilize the tray and contents.	Acceptance criterion: 3 consecutive half-cycles performed for each of the two sizes of trays will demonstrate complete inactivation of all biologic indicators; A minimum SAL of 10^{-6} is achieved if the Instructions for Use are followed	Pass
Dry time	The purpose of this test is to validate that the sterilization instructions listed in the Instructions for Use appropriately dry the wrapped tray for storage.	Acceptance criterion: Using pre-cycle and post-cycle weights, the weight gain after drying will not exceed ± 3%	Pass
Life Cycle / Simulated Use Life Validation FDA Guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* (issued March 2015)	The purpose of this test is to validate the service life of the trays as stated in the Instructions for Use.	Acceptance criteria: Visual inspection, component dimensional fit verification, functional closure/latch verification for 101 use cycles	Pass
Biocompatibility of Subject Device (by cytotoxicity testing) ANSI/AAMI/ISO 10993-5 ANSI/AAMI/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: Non-cytotoxic if ≤ 30% reduction of L-929 cell viability 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.

COMPARISON TO MARKETED PREDICATE DEVICE

The subject device is similar in indications and design principles to the predicate device. Provided at the end of this summary is a table comparing the Indications for Use Statements and the technological characteristics of the subject device and the predicate device.

The subject device and the predicate device K171713 have the same intended use, the same product classification and product code (KCT), and have similar Indications for Use statements.

Except for the names of the devices and details concerning the weights of the empty and loaded trays, the Indications for Use (IFU) statement for the subject device is identical to that of the predicate device K171713. Minor differences in the wording of the IFU do not change the intended use.

The subject device and the predicate device K171713 are reusable rigid sterilization trays used to organize and protect the instruments that are sterilized by the healthcare provider. Components of the subject device and the predicate device K171713 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 K171713 include components manufactured from polyphenylsulfone and silicone, and both devices are provided in one overall size and two configurations. The overall dimensions of the subject device are similar to the overall dimensions for the predicate devices K171713. The vent to volume ratio of the subject device is similar to the vent to volume ratio of the predicate device K171713.

The subject device was subjected to use life testing for 101 cycles, and the predicate device K171713 was subjected to use life testing for 60 cycles.

Minor differences in the dimensions, sizes, or designs between the subject device and the predicate device K171713 do not create different questions of safety and effectiveness relative to the predicate device because these differences are related to the specific designs features and system components, and are supported by the cleaning validation, sterilization validation, and use life testing performed.

Comparison of Technological Characteristics

Attribute	Subject Device K201878 ST-Z5 Z-Systems AG	Primary Predicate Device K171713 Neodent Instrument Kits JJGC Indústria e Comércio de Materiais Dentários S.A.	Comparison
Indications for Use Statement	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.	Neodent Instrument Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Neodent Instrument Kits are intended to allow sterilization of the enclosed medical devices. Neodent Instrument Kits require the use of FDA cleared wrap to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilization wrap that is FDA-cleared for the indicated cycles, and moist heat (steam) sterilized using one of the following cycles: Fractionated vacuum (pre-vacuum) – Exposure at 132 °C for 4 minutes, 20 minute dry time Gravity displacement – Exposure at 132 °C for 15 minutes, 20 minute dry time Neodent Instrument Kits are intended for sterilization of non-porous loads. The GM/WS Surgical Kit Case maximum load weight is 125 grams. The GM Surgical Kit Case maximum load weight is 113 grams. Neodent Instrument Kits are recommended not to be stacked during sterilization.	Similar
Product Code	KCT	KCT	Same
Design	Rigid polymer base, lid, and removable inner tray	Rigid polymer base, lid, and removable inner tray	Same
Materials	Polyphenylsulfone (Radel® R-5000) [lid, base, tray] Medical grade silicone [grommets/holders]	Polyphenylsulfone (Radel® R5000) [lid] Polysulfone [base, tray] Medical grade silicone	Similar
Materials compatible with Sterilization Method	Yes	Yes	Same
Perforated	Yes; allows moist heat (steam) penetration to achieve sterilization	Yes; allows moist heat (steam) penetration to achieve sterilization	Same
Reusable	Yes	Yes	Same
Number of Overall Sizes	1	1	Same
Number of Configurations	2	2	Same
Number of uses	101	*Not stated in 510(k) Summary*	n/a
Overall Dimensions	185.1 mm Length x 133.6 mm Width x 61.5 mm Height	264 mm Width x 163 mm Length x 54 mm Height	Similar
Vent to Volume Ratio	0.01596 cm^2 / cm^3 (0.0405 in^2 / in^3)	0.0102 cm^2 / cm^3 (0.0259 in^2 / in^3)	Similar
Reusable	Yes	Yes	Same
Use Life Testing	Reusable up to 101 cycles Assembled, sterilized Visual inspection Component dimensional fit verification Functional closure (lid-base latch) verification	Reusable up to 60 times; *number not stated in 510(k) Summary, but in publicly available labeling* Assembled/disassembled, cleaned, sterilized Visual inspection Component dimensional fit verification Functional closure (lid-base latch) verification	Similar
Sterilization Method			
Sterilant	Moist heat (steam)	Moist heat (steam)	Same
Cycles	Fractionated vacuum (pre-vacuum) Exposure at 132 °C (270 °F) for 4 minutes with 20 minutes drying time.	Gravity displacement and fractionated vacuum (pre-vacuum) *Cycle parameters not in 510(k) Summary*	Similar
Sterile Barrier	Sterilization wrap, FDA cleared for indicated method and cycle	Sterilization wrap, FDA cleared for indicated method and cycles	Same

CONCLUSION

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.