July 22, 2025

Talladium España, SL
℅ Rebecca Kattan
Regulatory Specialist
PaxMed International, LLC
12264 El Camino Real
Suite 400
San Diego, California 92130

Re: K243425
Trade/Device Name: Guided DAS Surgical Kit
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: June 3, 2025
Received: June 3, 2025

Dear Rebecca Kattan:

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: 2025.07.22 16:53:22 -04'00'

Stephen Anisko
Acting Assistant 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.*

Submission Number *(if known)*

K243425

Device Name

Guided DAS Surgical Kit

Indications for Use *(Describe)*

Guided DAS Surgical Kit is intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Guided DAS Surgical Kit is intended to allow sterilization of the enclosed medical devices.

Guided DAS Surgical Kit requires the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices.

The kit is to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycle, and moist heat (steam) sterilized using the following cycle: dynamic air removal steam sterilization- Exposure at 132 °C for 4 minutes and 30 minutes dry time.

Guided DAS Surgical Kit is intended for sterilization of non-porous loads.

Guided DAS Surgical Kit is recommended not to be stacked during sterilization.

The combined weight of the Guided DAS Surgical Kit and the associated instruments is 760 grams.

The weight of the empty Guided DAS Surgical Kit is 600 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.**

# 510(k) Summary

## K243425
## Talladium España, SL
## Guided DAS Surgical Kit
## July 22, 2025

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. ADMINISTRATIVE INFORMATION

| | |
|---|---|
| Manufacturer Name | Talladium España, SL<br>Virginia Woolf, 17<br>Lleida, Lleida, ES 25005<br>Telephone +34 973-289-580 |
| Official Contact | Xavier Soca Filella, General Manager |
| Representative/Consultant | Rebecca E. Kattan, PhD<br>Kevin A. Thomas, PhD<br>Floyd G. Larson, MS, MBA<br>PaxMed International, LLC<br>12264 El Camino Real, Suite 400<br>San Diego, CA 92130<br>Telephone: +1 858-792-1235<br>Fax: +1 858-792-1236<br>Email: rkattan@paxmed.com<br>kthomas@paxmed.com<br>flarson@paxmed.com |

2. DEVICE NAME AND CLASSIFICATION

| | |
|---|---|
| Trade/Device Name | Guided DAS Surgical Kit |
| 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 Health Technology 4<br>(OHT 4: Surgical and Infection Control Devices) |
| Reviewing Division | Division of Health Technology 4 C (Infection Control Devices) |

3. PREDICATE DEVICE INFORMATION

Primary predicate device is:
K201878, ST-Z5, Z-Systems AG.

## 4. INDICATIONS FOR USE STATEMENT

Guided DAS Surgical Kit is intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Guided DAS Surgical Kit is intended to allow sterilization of the enclosed medical devices.

Guided DAS Surgical Kit requires the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices.

The kit is to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycle, and moist heat (steam) sterilized using the following cycle: dynamic air removal steam sterilization-Exposure at 132 °C for 4 minutes and 30 minutes dry time.

Guided DAS Surgical Kit is intended for sterilization of non-porous loads.

Guided DAS Surgical Kit is recommended not to be stacked during sterilization.

The combined weight of the Guided DAS Surgical Kit and the associated instruments is 760 grams.

The weight of the empty Guided DAS Surgical Kit is 600 grams.

## 5. DEVICE DESCRIPTION

The subject device tray is to be used to organize and protect the instruments that are sterilized by the healthcare provider. The base, inner tray, and lid components are designed to be integrated into a single unit (the complete tray) which contains and protects the interior components during sterilization. The lid latches to the base to secure the tray into a single unit. The base, inner tray, and lid components 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 kits are manufactured from silicone.

The subject device comes in one (1) size and one (1) configuration, while the predicate device K201878 is provided in one (1) size and two (2) configurations. The subject device and the predicate device have similar overall dimensions, enclose similar volumes, and have similar vent to volume ratios. Differences in the dimensions and vent to volume ratios between the subject device and the predicate device are mitigated by the sterilization validation performed.

## 6. TECHNOLOGICAL CHARACTERISTICS COMPARISON

The subject device is compared in intended use to the predicate device K201878. The subject device and the predicate device K201878 have the same intended use, the same product classification and product code (KCT) and have similar Indications for Use statements. Components of the subject device and the predicate device K201878 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 basis for the belief of Talladium España, SL that the subject device compares favorably to the predicate device is summarized in the following Table of Technological Characteristics Comparison.

## Table of Technological Characteristics Comparison

| Attribute | Subject Device | Primary Predicate Device | Comparison |
|---|---|---|---|
| | **K243425**<br>Guided DAS Surgical Kit<br>Talladium España, SL | **K201878**<br>ST-Z5<br>Z-Systems AG | |
| Indications for Use Statement | Guided DAS Surgical Kit is intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Guided DAS Surgical Kit is intended to allow sterilization of the enclosed medical devices.<br><br>Guided DAS Surgical Kit requires the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices.<br><br>The kit is to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycle, and moist heat (steam) sterilized using the following cycle: dynamic air removal steam sterilization- Exposure at 132 °C for 4 minutes and 30 minutes dry time.<br><br>Guided DAS Surgical Kit is intended for sterilization of non-porous loads.<br><br>Guided DAS Surgical Kit is recommended not to be stacked during sterilization.<br><br>The combined weight of the Guided DAS Surgical Kit and the associated instruments is 760 grams.<br><br>The weight of the empty Guided DAS Surgical Kit is 600 grams. | 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.<br><br>ST-Z5 surgical trays require the use of an FDA cleared wrap to maintain the sterility of the enclosed devices.<br><br>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:<br>Pre-vacuum steam: 132 °C (270 °F) for 4 minutes with 20 minutes drying time.<br>ST-Z5 surgical trays are intended for sterilization of non-porous loads.<br>ST-Z5 surgical trays are recommended not to be stacked during sterilization.<br>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.<br><br>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. | Similar |
| Intended Use | This tray is designed to hold various dental surgical drills and tools to organize and protect the instruments that are sterilized in the trays by the healthcare provider. | This tray is designed to hold various dental surgical drills and tools to organize and protect the instruments that are sterilized in the trays by the healthcare provider. | Same |
| 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®) [lid, base, tray]<br>Medical grade silicone [grommets/holders] | Polyphenylsulfone (Radel® R-5000) [lid, base, tray] Medical grade silicone [grommets/holders] | Same |
| 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 | 1 | 2 | Similar |
| Number of uses | 50 | 101 | Similar |
| Overall Dimensions | 264.67 mm Length x 145.85 mm Width x 61.02 mm Height | 185.1 mm Length x 133.6 mm Width x 61.5 mm Height | Similar |
| Vent to Volume Ratio | 0.01233 $cm^2$ /$cm^3$ (0.001233 $mm^2$ /$mm^3$) | 0.01596 $cm^2$ / $cm^3$ | Similar |
| Reusable | Yes | Yes | Same |
| Use Life Testing | Reusable up to 50 cycles<br>Assembled, sterilized<br>Visual inspection<br>Component dimensional fit verification Functional closure (lid-base latch) verification | Reusable up to 101 cycles<br>Assembled, sterilized<br>Visual inspection<br>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)<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 | Same |

## 7.0 SUMMARY OF NONCLINICAL TESTING

Provided below are the nonclinical test methodologies performed to demonstrate that the subject device meets the acceptance criteria of the standard.

**Summary of Nonclinical Testing Table**

| Test Methodology | Purpose | Results |
|---|---|---|
| Manual 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. | 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. | 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. | 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. | Pass |
| Biocompatibility of Subject Device 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. | 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.

## 8.0 CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the subject device in this 510(k) submission, Guided DAS Surgical Kit, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K201878.