



June 20, 2025

MicroAire Surgical Instruments, LLC
Ashley Sanguinetti
Senior Regulatory Affairs Specialist
3590 Grand Forks Blvd.
Charlottesville, Virginia 22911

Re: K243589

Trade/Device Name: PAL Sterilization Case
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: May 21, 2025
Received: May 21, 2025

Dear Ashley Sanguinetti:

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. Digitally signed by
Anisko -S Stephen A. Anisko -S
Date: 2025.06.20
17:34:35 -04'00'

for: Christopher Dugard
Director
DHT4C: Division of Infection Control
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K243589

Device Name
PAL Sterilization Case

Indications for Use (Describe)

The PAL Sterilization Case is a reusable sterilization case intended to provide storage for the PAL handpiece, the PAL cable, and 4 PAL cannulas during sterilization, storage, and transportation within the hospital environment. The PAL Sterilization Case is only intended to maintain sterility of the enclosed components during autoclave sterilization when used in conjunction with FDA-cleared sterilization wraps. The PAL Sterilization Case has only been evaluated for a non-stacked configuration. The validated steam sterilization parameters are listed below:

Cycle Type	Exposure Temperature	Exposure Time (minutes)	Minimum Dry Time (minutes)	Compatible Sterile Barriers
Pre-Vacuum	132 °C (270 °F)	4 minutes	20 minutes	Wrap(s)
Gravity	121 °C (250 °F)	30 minutes	20 minutes	Wrap(s)

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

MicroAire PAL Sterilization Case

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

1. Submitter

MicroAire Surgical Instruments, LLC
3590 Grand Forks Boulevard
Charlottesville, Virginia 22911
USA

2. Primary Contact Person

Ashley Sanguinetti
Senior Regulatory Affairs Specialist
MicroAire Surgical Instruments, LLC
Phone: (434) 975-8344
Fax: (434) 975-4144
Email: ashley.sanguinetti@microaire.com

3. Date Prepared

June 18, 2025

4. Device Identification

Trade/Proprietary Name:	PAL Sterilization Case
Common/Usual Name:	Sterilization Case
Regulation Number:	21 CFR 880.6850
Regulation Name:	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Regulatory Class:	Class 2
Product Code:	KCT
Classification Panel:	General Hospital

5. Legally Marketed Predicate Device(s)

Device name: Sonicision™ reusable sterilization tray
510(k) number: K180915
Manufacturer: Covidien, LLC

No reference devices were used in this submission.

6. Indications for Use Statement

The PAL® Sterilization Case is a reusable sterilization case intended to provide storage for the PAL® handpiece, the PAL® cable, and 4 PAL® cannulas during sterilization, storage, and transportation within the hospital environment. The PAL® Sterilization Case is only intended to maintain sterility of the enclosed components during autoclave sterilization when used in conjunction with FDA-cleared sterilization wraps. The PAL® Sterilization Case has only been evaluated for a non-stacked configuration. The validated steam sterilization cycle parameters are listed below:

Cycle Type	Exposure Temperature	Exposure Time (minutes)	Minimum Dry Time (minutes)	Compatible Sterile Barriers
Pre-Vacuum	132 °C (270 °F)	4	20	Wrap(s)
Gravity	121 °C (250 °F)	30	20	Wrap(s)

7. Device Description

The MicroAire PAL Sterilization Case is a non-surgical, non-patient contacting, accessory to the already existing PAL (Power-Assisted Liposuction) System (cleared for market under K212024, K171286 and K220318), designed to contain reusable surgical instruments during steam sterilization. The case is designed to contain four (4) PAL Multi-Use Cannulas, one (1) PAL Electric Handpiece, and one (1) PAL Handpiece Cable. The subject product scope only includes the sterilization case, constructed of a separable base and lid, as illustrated in Figure 11-A.

Figure 11-A

PAL Sterilization Case (PAL-CASE)




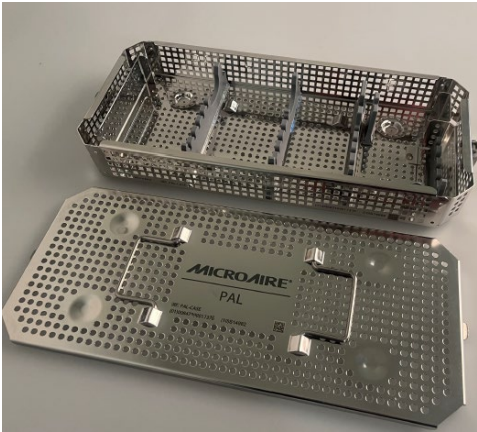
The PAL Sterilization Case (subject device) is a stainless-steel case comprised of a separable lid and base. These two components latch together via the latch mechanisms on either side of the base which mate with the flanges on either side of the lid. Inside the case there are silicone mounts for a PAL handpiece, cable, and 4 cannulas (30 cm or less in length). The sterilization case is used to steam sterilize its contents via standard gravity or dynamic air removal autoclave processes. The subject device is a non-surgical, non-patient contacting, accessory device to the MicroAire PAL System. The subject device allows a user to organize and transport PAL reusable surgical instruments before, during, and after steam sterilization. The case is provided non-sterile and contains silicon mounting brackets to keep the devices in place, and a perforated stainless-steel enclosure to allow penetration of steam. The case has an overall footprint of approximately 16" x 6" x 2". Its construction of 1mm thick stainless steel and silicone make it lightweight and easy to transport when fully loaded with instruments. The lid also has two carrying handles on its lid for easy transport.

8. Technological Characteristics Comparison

The following table compares the subject device MicroAire PAL Sterilization Case with the predicate device Covidien Ilc, Sonicision™ reusable sterilization tray (K180915) with respect to indications for use, mechanisms of operation, technological characteristics, materials, and performance testing.

Table 11-A
Comparison to Predicate

Characteristic	Predicate Device Sonicision™ Reusable Sterilization Tray, K180915	Subject Device MicroAire, PAL® Sterilization Case, K243589	Device Comparison																																								
CLASSIFICATION & INDICATIONS																																											
FDA Classification	Class II	Class II	Same																																								
FDA Product Code	KCT	KCT	Same																																								
FDA Classification Name	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories	Same																																								
Indications for Use	<p>The Sonicision™ reusable sterilization tray is intended to provide storage for the compatible reusable generator and reusable battery insertion guides during sterilization, storage, and transportation within the hospital environment. The Sonicision™ reusable sterilization tray is only intended to maintain sterility of the enclosed components during autoclave sterilization when used in conjunction with an FDA-cleared sterilization wrap or rigid container (validated with Aesculap™* rigid container model JN741/JK789). The sterilization tray has only been evaluated for a non-stacked configuration.</p> <p>The validated sterilization cycle parameters are as follows: Steam Sterilization Cycles</p> <table border="1"> <thead> <tr> <th>Cycle Type</th> <th>Exposure Temperature</th> <th>Exposure Time (minutes)</th> <th>Minimum Dry Time¹ (minutes)</th> <th>Compatible Sterile Barriers</th> </tr> </thead> <tbody> <tr> <td>Pre-Vacuum</td> <td>132 °C (270 °F)</td> <td>4</td> <td>40</td> <td>Wrap(s) and rigid cotainers²</td> </tr> <tr> <td>Pre-Vacuum</td> <td>135 °C (275 °F)</td> <td>3</td> <td>40</td> <td>Wrap(s) and rigid cotainers²</td> </tr> <tr> <td>Gravity</td> <td>132 °C (270 °F)</td> <td>15</td> <td>40</td> <td>Wrap(s)</td> </tr> <tr> <td>Gravity</td> <td>135 °C (275 °F)</td> <td>10</td> <td>30</td> <td>Wrap(s)</td> </tr> </tbody> </table> <p>¹ Due to the variations in autoclave sterilization equipment, actual dry times may vary from the minimum dry times validated for this product. ² Validated with Aesculap™* rigid container model JN741/JK789.</p>	Cycle Type	Exposure Temperature	Exposure Time (minutes)	Minimum Dry Time ¹ (minutes)	Compatible Sterile Barriers	Pre-Vacuum	132 °C (270 °F)	4	40	Wrap(s) and rigid cotainers ²	Pre-Vacuum	135 °C (275 °F)	3	40	Wrap(s) and rigid cotainers ²	Gravity	132 °C (270 °F)	15	40	Wrap(s)	Gravity	135 °C (275 °F)	10	30	Wrap(s)	<p>The PAL Sterilization Case is a reusable sterilization case intended to provide storage for the PAL handpiece, the PAL cable, and 4 PAL cannulas during sterilization, storage, and transportation within the hospital environment. The PAL Sterilization Case is only intended to maintain sterility of the enclosed components during autoclave sterilization when used in conjunction with FDA-cleared sterilization wraps. The PAL Sterilization Case has only been evaluated for a non-stacked configuration.</p> <p>The validated sterilization cycle parameters are as follows: Steam Sterilization Cycles</p> <table border="1"> <thead> <tr> <th>Cycle Type</th> <th>Exposure Temperature</th> <th>Exposure Time (minutes)</th> <th>Minimum Dry Time (minutes)</th> <th>Compatible Sterile Barriers</th> </tr> </thead> <tbody> <tr> <td>Pre-Vacuum</td> <td>132 °C (270 °F)</td> <td>4</td> <td>20</td> <td>Wrap(s)</td> </tr> <tr> <td>Gravity</td> <td>121 °C (250 °F)</td> <td>30</td> <td>20</td> <td>Wrap(s)</td> </tr> </tbody> </table>	Cycle Type	Exposure Temperature	Exposure Time (minutes)	Minimum Dry Time (minutes)	Compatible Sterile Barriers	Pre-Vacuum	132 °C (270 °F)	4	20	Wrap(s)	Gravity	121 °C (250 °F)	30	20	Wrap(s)	Similar
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Characteristic	Predicate Device Sonication™ Reusable Sterilization Tray, K180915	Subject Device MicroAire, PAL® Sterilization Case, K243589	Device Comparison
SUMMARY OF PHYSICAL CHARACTERISTICS			
Image			Similar
Material Specifications	<ul style="list-style-type: none"> • Base: Polyphenylsulfone • Lid: Stainless Steel 	<ul style="list-style-type: none"> • Base and Lid: 304L and 304 stainless steels • Perforation inserts: Medical Grade Gray Silicone 	Same/ Different
Dimensions	LxWxH: 8.5" x 11.0" x 3.0"	LxWxH: 15.91" x 6.55" x 2.42"	Similar
SUMMARY OF TECHNOLOGICAL CHARACTERISTICS			
Case Type	Sterilization Case	Sterilization Case	Same
Enclosed devices for sterilization	The tray can contain at a maximum: One (1) Sonication™ Reusable Generator, Two (2) Sonication™ Reusable Battery Insertion Guides.	The tray can contain at a maximum: One (1) PAL Handpiece One (1) PAL Cable Up to four (4) PAL Cannulas (30 cm or less in length). The sterilization case is an accessory to the approved PAL System, designed to contain reusable surgical instruments during steam sterilization. The PAL Sterilization Case is a stainless-steel case comprised of a separable lid and base. These two components latch together via the latch mechanisms on either side of the base which mate with the flanges on either side of the lid. Inside the case there are silicone mounts for a PAL handpiece, cable, and 4 cannulas	Different

Characteristic	Predicate Device Sonicision™ Reusable Sterilization Tray, K180915	Subject Device MicroAire, PAL® Sterilization Case, K243589	Device Comparison
		(30cm or less in length). The sterilization case is used to steam sterilize its contents via standard gravity or dynamic air removal autoclave processes. The silicone inserts hold the instruments in place. The case can be double wrapped using FDA-cleared sterilization wraps and loaded into the autoclave.	
Device Description	The Sonicision Sterilization Tray is a reusable, optional accessory to the Sonicision System (cleared through K180149). This device is specially made to enclose up to one Sonicision Reusable Generator and up to two Sonicision Reusable Battery Insertion Guides in order to provide storage during sterilization, storage, and transportation within the hospital environment.	The PAL Sterilization Case is a reusable, optional accessory to the approved PAL System (cleared through K212024). This device is specially made to enclose up to one PAL Electric Handpiece, one PAL Cable and up to four PAL Multi-use Cannulas (30 cm or less in length) in order to provide storage during sterilization, storage, and transportation within the hospital environment.	Similar
Sterilization methods	Steam (Pre-vacuum and Gravity)	Steam (Pre-vacuum and Gravity)	Same
Steam sterilization parameters	<u>132 °C Pre-vacuum Steam Cycle</u> Exposure temperature: 270 °F (132 °C) Exposure time: 4 minutes Minimum dry time: 40 minutes <u>135 °C Pre-vacuum Steam Cycle</u> Exposure temperature: 275 °F (135 °C) Exposure time: 3 minutes Minimum dry time: 40 minutes	<u>132 °C Pre-vacuum Steam Cycle</u> Exposure temperature: 270 °F (132 °C) Exposure time: 4 minutes Minimum dry time: 20 minutes	Similar
	<u>132 °C Gravity Steam Cycle</u> Exposure temperature: 270 °F (132 °C) Exposure time: 15 minutes Minimum dry time: 40 minutes <u>135 °C Gravity Steam Cycle</u> Exposure temperature: 275 °F (135 °C) Exposure time: 10 minutes Minimum dry time: 30 minutes	<u>121 °C Gravity Steam Cycle</u> Exposure temperature: 250 °F (121 °C) Exposure time: 30 minutes Minimum dry time: 20 minutes	Similar
Stacking	Do not stack cases and trays in the sterilization chamber.	Do not stack cases and trays in the sterilization chamber.	Same
Maximum Load Capacity	< 1800 grams (3.97 pounds, including tray)	5.582 lbs ± 0.026 lbs (including case)	Different

9. Non-Clinical Performance Data

Non-clinical testing was performed to verify and validate the design of the PAL Sterilization Case against specified design requirements and to assure conformance with applicable recognized national consensus standards and FDA Guidance documents. The PAL Sterilization Case passed all non-clinical testing.

The PAL Sterilization Case complies with all applicable voluntary consensus standards and FDA Guidance documents for Sterilization Cases (per Product Code - KCT), shown in the table below.

Table 11-B
Summary of Non-Clinical Testing

Test Description	Applicable Standards	Acceptance Criteria	Test Results
PAL Sterilization Case Gravity Steam Sterilization Validation	<ul style="list-style-type: none"> ANSI/AAMI ST77:2013/(R)2018 AAMI TIR12:2020 ISO 17665:2024 FDA Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling 	A full cycle of 30 minutes at 121°C using gravity air displacement for the PAL Sterilization Case in a double-wrapped configuration.	Passed The results of the study found that a 121°C, 30-minute gravity sterilization and dry time of 20 minutes is sufficient to sterilize (and dry) the PAL product family (not including cannulas over 30 cm in length) to a Sterility Assurance Level (SAL) of 10 ⁻⁶ in the PAL Sterilization Case (PAL-CASE) in a double wrapped configuration.
PAL Sterilization Case Pre-Vacuum Steam Sterilization Validation	<ul style="list-style-type: none"> ANSI/AAMI ST77:2013/(R)2018 AAMI TIR12:2020 ISO 17665:2024 FDA Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling 	A full cycle of four (4) minutes at 132°C using pre-vacuum air removal for the PAL Sterilization Case in a double wrapped configuration.	Passed The results of the study found that a 132°C, 4-minute pre-vacuum sterilization and dry time of 20 minutes is sufficient to sterilize (and dry) the PAL product family (not including cannulas over 30 cm in length) to a Sterility Assurance Level (SAL) of 10 ⁻⁶ in the PAL Sterilization Case (PAL-CASE) in a double wrapped configuration.
Validation of Automated and Manual Cleaning Methods for PAL Sterilization Case	<ul style="list-style-type: none"> AAMI ST98:2022 FDA Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling 	In accordance with ST98 requirements. There shall be no visible evidence of test soil remaining on any surface of the device post cleaning from a distance of 18 inches with 20/20 vision.	Passed The results confirm that MicroAire's draft automated and manual cleaning instructions for the PAL Sterilization Case (PAL-CASE) are effective in removing soil from the devices to the point that they are considered cleaned.
Design Verification - PAL Sterilization Case Weight	<ul style="list-style-type: none"> ANSI/AAMI ST77:2013/(R)2018 (for sample size) 	There shall be 90% confidence that the mean weight of the PAL Sterilization Case population is less than 25lb while containing the following: one PAL Electric Handpiece, one PAL Instrument Cable, and four PAL Cannula.	Passed There is a 90% confidence that the fully loaded PAL Sterilization case population has a mean weight of 5.582 lb ± 0.026 lb, which is within the required upper bound of 25 lb.

10. Clinical Performance Data

The PAL Sterilization Case has not been the subject of clinical testing.

11. Conclusion

The conclusions drawn from nonclinical testing demonstrate that the subject device, K243589, Microaire PAL Sterilization Case, is as safe, as effective and performs as well or better than the legally marketed predicate device, K180915 Covidien Sonicision™.