July 23, 2025

Merit Medical Systems, Inc.
David Thomas
Principal Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K251265
Trade/Device Name: Resilience Fully Covered Esophageal Stent System
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: Class II
Product Code: ESW
Dated: April 24, 2025
Received: April 24, 2025

Dear David 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 (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,

SIVAKAMI VENKATACHALAM -S

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251265

Please provide the device trade name(s).

Resilience Fully Covered Esophageal Stent System

Please provide your Indications for Use below.

The Resilience Fully Covered Esophageal Stent System is intended for maintaining esophageal luminal patency in patients with esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and for occlusion of esophageal fistulae.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #:

510(k) Summary

Prepared on: 2025-06-10

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Merit Medical Systems, Inc.
Applicant Address	1600 West Merit Parkway South Jordan UT 84095 United States
Applicant Contact Telephone	801-316-4956
Applicant Contact	Mr. David Thomas
Applicant Contact Email	david.thomas@merit.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Resilience Fully Covered Esophageal Stent System
Common Name	Esophageal prosthesis
Classification Name	Prosthesis, Esophageal
Regulation Number	878.3610
Product Code(s)	ESW

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K111611	EndoMAXX Fully Covered Esophageal Stent	ESW

Device Description Summary

21 CFR 807.92(a)(4)

The MERIT ENDOTEK® Resilience™ Fully Covered Esophageal Stent System is a through-the-scope system comprised of two components: the radiopaque self-expanding nitinol stent and the delivery system. The stent is completely covered with a biocompatible silicone membrane. Stent expansion results from the physical properties of the metal and the proprietary geometry. The stent is designed with unique geometrical features at the distal and proximal ends to anchor the stent and resist migration. The proximal and distal ends of the stent are threaded with a suture intended for use in repositioning and removal of the stent.

The stents come in nine (9) sizes, comprising all combinations of three lengths (5cm, 6cm, and 7cm) and three midbody diameters (14mm, 17mm, and 20mm). The midbody lengths are 1cm, 2cm, and 3cm with the flared ends comprising the remaining length. The ends of the stents are larger in diameter than the midbody.

There is one 10.5Fr delivery system used to deploy all 9 stents.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Resilience Fully Covered Esophageal Stent System is intended for maintaining esophageal luminal patency in patients with esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and for occlusion of esophageal fistulae.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are identical to the predicate device (EndoMAXX Fully Covered Esophageal Stent).

Technological Comparison 21 CFR 807.92(a)(6)

Both stents are self expanding nitinol stents with a silicone covering. The Resilience stent can be delivered through the scope with a 10.5 F delivery catheter which differs from the predicate stent which has a larger 18.3 F catheter. It is available in three (3) lengths, 50, 60 and 70 mm and mid-body diameters of 14, 17 and 20 mm which differ from the predicate device that is 19 and 23 mm for mid-body diameters and available in four (4) lengths of 70, 100, 120 and 150 mm. The stent design differs also in that it is wider at the ends that are flared at 24, 27 and 28 mm depending on the mid-body diameter to anchor the stent and to resist migration. The Resilience stent is also supplied sterile which differs from the EndoMAXX stent that was supplied non-sterile.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical testing included testing of the following:
Stent Verification testing: dimensions and condition after deployment and removal, suture purse strings the stent, stent springs back after purse stringing, repositioning with forceps, suture withstands forceps, removal force, flare retention force, and radial pressure forces (compression/expansion), tensile strength, food flow.

Testing post-fatigue was repeated for stent condition, removal force, flare retention force, radial pressure forces (compression/expansion) and tensile strength.

Delivery system testing included guidewire compatibility, catheter working length, catheter outer diameters, safety functionality, stent deployment force, stent repositioning after partial deployment, stent expansion after deployment, deployment accuracy, delivery system condition after deployment and removal, tip-to-guidewire lumen bond strength, outer sheath-to-connector bond strength, egress plug-to-guidewire lumen bond strength,

All of the above testing passed the predetermined specifications.

Additional tests for information only were: stent foreshortening, post-fatigue stent dimensions, post-fatigue stent removal force, stent pinch forces before and after fatigue, and post-fatigue suture tensile-to-break and stent length in catheter pod, stent pod outer diameters, gap measurements, constrained stent length, condition of stent ends, post-deployment device inspection.

Additional testing included:
Corrosion testing (met all predetermined corrosion performance requirements)
MRI compatibility (MR conditional in accordance to FDA's guidance "Testing and Labeling Devices for Safety in the Magnetic Resonance (MR) Environment"

Biocompatibility testing met the requirements of the FDA Final Guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing with a risk management process' "".

Design validation was performed and all design validation requirements were met.

The device met all predetermined testing requirements that demonstrates the device is a safe and affective and performs as well as the legally marketed device identified above.