August 20, 2025

Liofilchem s. r. l.
℅ Laura Koeth
President
Laboratory Specialists, Inc.
26214 Center Ridge Road
Westlake, Ohio 44145

Re: K251580
Trade/Device Name: MTS Sulbactam-Durlobactam 0.004/4 - 64/4 µg/mL (SUD)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: JWY
Dated: May 22, 2025
Received: May 23, 2025

Dear Laura Koeth:

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.

Please note that if you modify your IVD in the future to exceed any of the limitations to the exemption found in 21 CFR 866.9(c), your device will require a new 510(k) prior to marketing this device in the United States and will not be exempt from the premarket notification requirements so long as it exceeds the limitations to the exemption found in 21 CFR 866.9.

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 and Part 809); 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,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
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)*
K251580

Device Name

MTS Sulbactam-Durlobactam 0.004/4 - 64/4 µg/ml (SUD)

Indications for Use *(Describe)*

The MTS (MIC Test Strip) Sulbactam-Durlobactam 0.004/4-64/4 µg/ml is a quantitative method intended for the in vitro determination of antimicrobial susceptibility of bacteria. MTS consists of specialized paper impregnated with a pre-defined concentration gradient of an antimicrobial agent, which is used to determine the minimum inhibitory concentration (MIC) in µg/ml of antimicrobial agents against bacteria as tested on agar media using overnight incubation and manual reading procedures. MTS Sulbactam- Durlobactam at concentrations of 0.004/4-64/4 µg/ml should be interpreted at 16-20 hours of incubation.

Testing with MTS Sulbactam-Durlobactam at concentrations of 0.004/4-64/4 µg/mL is indicated for Acinetobacter baumannii calcoaceticus complex as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC).

The MTS Sulbactam-Durlobactam 0.004/4-64/4 µg/mL has demonstrated acceptable performance with the following organisms:

Acinetobacter baumannii calcoaceticus complex

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) EXECUTIVE SUMMARY:

I. SUBMITTER and LEGAL OWNER:

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Via Scozia zona ind.le
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Contact Person and 510(k) Preparer:
Laura M. Koeth, President
Laboratory Specialists, Inc.

Date 510(k) Prepared: July 10, 2025

II. 510(k) DEVICE

510(k) Number:	K251580
Name of Device:	MTS Sulbactam-Durlobactam 0.004/4 - 64/4 µg/mL
Common Name:	Manual Antimicrobial Susceptibility Test System
Classification:	Antimicrobial Susceptibility Test Powder 866.1640
Regulatory Class:	Class II
Product Code:	JWY – Manual Antimicrobial Test Systems

III. PREDICATE DEVICES Liofilchem MTS, vancomycin K153687
These predicate products have not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

MTS Sulbactam-Durlobactam 0.004/4 - 64/4 µg/mL is made of special high-quality paper impregnated with a predefined concentration of gradient sulbactam across 15 two-fold dilutions like those of a conventional MIC method and durlobactam at a fixed concentration of 4 µg/mL. One side of the strip is labeled with the sulbactam-durlobactam code (SUD) and the MIC reading scale in µg/mL. When the MTS is applied onto an inoculated agar surface, the performed exponential gradient of antimicrobial agent diffuses into the agar for over an hour. After 16-20 hours incubation, a symmetrical inhibition ellipse centered along the strip is formed. The MIC is read directly from the scale in terms of µg/mL at the point where the edge of the inhibition ellipse intersects the MIC Test Strip. The MIC Test Strip (MTS) is single use only.

Sulbactam-durlobactam is an intravenous beta-lactam combination antibiotic used to treat hospital-acquired pneumonia and ventilator-associated bacterial pneumonia caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.

MTS is supplied in 3 different packaging options (no additional reagents are included). There is a 10- test box, a 30- test box and a 100-test box.

V. INDICATIONS FOR USE

The MTS (MIC Test Strip) Sulbactam-Durlobactam 0.004/4-64/4 µg/ml is a quantitative method intended for the in vitro determination of antimicrobial susceptibility of bacteria. MTS consists of specialized paper impregnated with a pre-defined concentration gradient of an antimicrobial agent, which is used to determine the minimum inhibitory concentration (MIC) in µg/ml of antimicrobial agents against bacteria as tested on agar media using overnight incubation and manual reading procedures. MTS Sulbactam-Durlobactam at concentrations of 0.004/4-64/4 µg/ml should be interpreted at 16-20 hours of incubation.

Testing with MTS Sulbactam-Durlobactam at concentrations of 0.004/4-64/4 µg/mL is indicated for *Acinetobacter baumannii calcoaceticus* complex as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC).

The MTS Sulbactam-Durlobactam 0.004/4-64/4 µg/mL has demonstrated acceptable performance with the following organisms:

Acinetobacter baumannii calcoaceticus complex

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Predicate Device Name:

Liofilchem MTS, vancomycin (VA) K153687

Comparison of 510(k) device with the predicates:

Substantial Equivalence Comparison		
Device & Predicate Device	**Device: MTS Sulbactam-Durlobactam (K251580)**	**Predicate: MTS Vancomycin K153687**
Intended Use:	Quantitative susceptibility to antimicrobial agents against *Acinetobacter baumannii-calcoaceticus* complex	Gram-positive
Antimicrobial Agent**:**	Sulbactam-Durlobactam (SUD)	Vancomycin (VA)
MTS Strip Material:	high quality paper impregnated with a predefined concentration of gradient antimicrobial agent	Same
Plate Media:	Mueller Hinton agar	Same
Inoculation:	Isolated colonies from culture in a suspension equivalent to 0.5 McFarland. Inoculum is applied to agar with swab manually or with rotation plate.	Same
Incubation:	35^{o}C ±2^{o}C for 16-20 hours	24 hours
Reading:	Manual; Interpret the MIC as 100%	Same
Result:	MIC in µg/mL MIC	Same

The differences between the two devices are related to the varying spectrum of activity of the two antimicrobial agents and the incubation duration differs because of the different bacterial species. These differences are included in each of the device IFU and do not affect the effectiveness of the device.

VII. PERFORMANCE DATA

The study design was in accordance with CDRH Guidance for Industry and FDA, Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems, August 28, 2009.

(a) Method comparison

Reference MIC panels were prepared with cation adjusted Mueller Hinton broth and tested according to CLSI broth microdilution guidelines (CLSI M7-A11). Clinical testing was performed at three sites and included testing of fresh clinical isolates by Sulbactam-Durlobactam MTS and reference broth microdilution MIC method. The challenge isolates were selected to include a range of sulbactam-durlobactam MIC results including resistant isolates; all challenge isolate testing of sulbactam-durlobactam MTS and reference MIC method was performed at one site (Laboratory Specialists, Inc.). Each of the three sites also tested Sulbactam-Durlobactam MTS for a set of 10 reproducibility isolates in triplicate on 3 days and results for each isolate were compared to the all site modal MIC for determination of the percentage of results within one dilution of the modal MIC (essential agreement). QC strain *A. baumannii* NCTC 13304 was tested at least 20 times by Sulbactam-Durlobactam MTS and reference MIC methods at each of the three sites and results compared to CLSI reference ranges (CLSI M100-S34).

Summary of performance data for combined clinical and challenge organism groups for *Acinetobacter baumannii calcoaceticus* complex

Total Tested	#EA	%EA	Total Eval	#EA of Eval	%EA of Eval	#CA	%CA	#R	#vmj	#maj	#min
588	572	97.3%	549	533	97.1%	545	92.7%	49	0	2	41

EA-essential agreement (+/- 1 dilution);Eval - evaluable; CA-category agreement;
R-resistant; vmj-very major, maj-major, min-minor errors

(b) Reproducibility

96.3% of MTS™ Sulbactam-Durlobactam results for *A. baumannii* (tested in triplicate at 3 sites on 3 days) were within a doubling dilution of reference broth microdilution results.

(c) Quality Control

The quality control strain, *A. baumannii*, NCTC 13304, was tested minimally 20 times by each testing site. Sulbactam-durlobactam MIC results for this quality control strain are shown in the following table and demonstrated acceptable results.

QC Organism	Expected Result	MIC µg/mL	Reference BMD Frequency				MTS Frequency			
			Site 1	Site 2	Site 3	All Sites	Site 1	Site 2	Site 3	All Sites
A.baumannii NCTC 13304	0.5-2 µg/mL	0.25				**0**				**0**
		0.5				**0**				**0**
		1	**19**	**54**	**24**	**97**		**52**	**12**	**64**
		2	**4**	**11**	**4**	**19**	**23**	**21**	**19**	**63**
		4				**0**				**0**

VIII. PROPOSED LABELLING

Interpretive criteria are the same as those recognized by FDA Susceptibility Testing Interpretive Criteria (STIC) as included in the package insert.

IX. CONCLUSION

The MTS Sulbactam-Durlobactam 0.004/4 - 64/4 µg/mL strip when tested against *Acinetobacter baumannii calcoaceticus* complex performed similar to reference broth microdilution methodology and supports a substantial equivalence decision.