April 17, 2026

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

Re: K260696
Trade/Device Name: MTS Gepotidacin 0.016-256 µg/mL
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: JWY
Dated: March 2, 2026
Received: March 3, 2026

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.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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,

Noel J. Gerald -S

Noel J. Gerald, Ph.D.
Deputy Division Director
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)*
K260696

Device Name
MTS Gepotidacin 0.016-256 µg/mL

Indications for Use *(Describe)*
The MTS (MIC Test Strip) Gepotidacin 0.016-256 µg/mL is a quantitative method intended for in vitro determination of antimicrobial susceptibility of bacteria. MTS consists of specialized paper impregnated with a predefined 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 Gepotidacin at concentrations of 0.016-256 µg/mL should be interpreted at 16-20 hours of incubation.

Testing with MTS Gepotidacin at concentrations of 0.016-256 µg/mL is indicated for Enterobacterales, Enterococcus faecalis, and Staphylococcus saprophyticus as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC).

The MTS Gepotidacin 0.016-256 µg/mL has demonstrated acceptable performance with the following organisms:

Enterobacterales (Citrobacter freundii complex, Escherichia coli, and Klebsiella pneumoniae)

Enterococcus faecalis

Staphylococcus saprophyticus

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) EXECUTIVE SUMMARY:

I. SUBMITTER and LEGAL OWNER:

Liofilchem® s.r.l.
Via Scozia zona ind.le
64026 Roseto degli Abruzzi (TE), Italy
Fabio Brocco, Chief Operating Officer
Phone: +39 0858930745

Contact Person and 510(k) Preparer:
Laura M. Koeth, President
Laboratory Specialists, Inc.

Date 510(k) Prepared: March 2, 2026

II. 510(k) DEVICE

510(k) Number:	
Name of Device:	MTS Gepotidacin 0.016-256 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 Gepotidacin 0.016-256 µg/mL is made of special high-quality paper impregnated with a predefined concentration of gradient gepotidacin across 15 two-fold dilutions like those of a conventional MIC method. One side of the strip is labeled with the gepotidacin code (GEP 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.

Gepotidacin is a novel, first-in-class triazaacenaphthylene antibiotic that selectively inhibits type IIA topoisomerases through a distinct binding site and unique mechanism. It is used to treat uncomplicated urinary tract infections (uUTI) caused by susceptible *Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii* complex, *Staphylococcus saprophyticus* and *Enterococcus faecalis*. It is also used to treat uncomplicated urogenital gonorrhea.

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) Gepotidacin 0.016-256 µg/mL is a quantitative method intended for in vitro determination of antimicrobial susceptibility of bacteria. MTS consists of specialized paper impregnated with a predefined 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 Gepotidacin at concentrations of 0.016-256 µg/mL should be interpreted at 16-20 hours of incubation.

Testing with MTS Gepotidacin at concentrations of 0.016-256 µg/mL is indicated for Enterobacterales, Enterococcus faecalis, and Staphylococcus saprophyticus as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC).

The MTS Gepotidacin 0.016-256 µg/mL has demonstrated acceptable performance with the following organisms:

Enterobacterales (*Citrobacter freundii complex, Escherichia coli, and Klebsiella pneumoniae*)

Enterococcus faecalis

Staphylococcus saprophyticus

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	
510(k) Device: MTS Gepotidacin	**MTS Vancomycin K153687**
Intended Use: Quantitative susceptibility to antimicrobial agents against Enterobacterales (*Citrobacter freundii complex, Escherichia coli,* and *Klebsiella pneumoniae), Enterococcus faecalis,* and *Staphylococcus saprophyticus*	Gram-positive
Antimicrobial Agent**:** Gepotidacin (GEP)	Vancomycin (VA)

Substantial Equivalence Comparison	
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 agent and bacterial species tested. These differences are not critical to the diagnostic use, 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

(b) Multiple studies that included gepotidacin testing by both broth microdilution (BMD) and MTS were used for this submission. In addition to three sites that provided testing in accordance with the typical 510(k) protocols, gepotidacin Phase 3 clinical data and surveillance data were utilized. Clinical testing was performed at four sites and included testing of fresh clinical isolates (44.1% tested within 6 months of collection). The challenge isolates were selected to include a range of gepotidacin MIC results including a limited number of resistant isolates; all challenge isolate testing of MTS Gepotidacin and broth microdilution MIC methods was performed at one site (Laboratory Specialists, Inc.). Each of the three sites also tested MTS Gepotidacin for a set of 18 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 strains *E. coli* ATCC 25922, *S. aureus* ATCC 29213 and *E. faecalis* ATCC 29212 were tested at least 20 times by MTS Gepotidacin and broth microdilution MIC methods at each of the three sites and results compared to CLSI reference ranges (CLSI M100-S35).

Summary of performance data for combined clinical and challenge organism groups.

Organism Species/Group	N	% Essential Agreement	% Category Agreement
Enterobacterales*[1]	12,435	97.6	98.5
E. faecalis	106	99.1	100
S. saprophyticus	871	98.3	99.8

**C. freundii complex, E. coli, K. pneumoniae*

[1]MTS Gepotidacin MIC values tended to be in exact agreement or at least one doubling dilution higher when testing *E. coli*

(c) Reproducibility

99.4% of MTS™ Gepotidacin results for 1 *C. freundii*, 4 *E. coli*, 3 *K. pneumoniae, 5 E. faecalis* and *5 S. saprophyticus* tested in triplicate at 3 sites on 3 days were within a doubling dilution of the all site modal MIC results.

(d) Quality Control

Each of three quality controls strains (*E. coli* ATCC 25922, *E. faecalis* ATCC 29212 and *S. aureus* ATCC 29213) was tested minimally 20 times by each testing site. Gepotidacin MIC results for these quality control strains are shown in the following table.

QC Organism	Expected Result (µg/mL)	MIC	Reference BMD Frequency				MTS Frequency					
		(µg/m)L	LSI	JMI	CLIN	All Sites	WF	LIO	LSI	JMI	CLIN	All Sites
E. coli ATCC 25922	1-4	0.5										
		1	11	144	162	**317**	20	3	10	13	18	**64**
		2	29	17	23	**69**			30	168	156	**354**
		4		3		**3**				6	4	**10**
		8										
E. faecalis ATCC 29212	1-4	0.5										
		1		1	27	**28**					4	**4**
		2	20	29	20	**69**	20	3	20		45	**88**
		4		2		**2**					1	**1**
		8										
		16		1		**1**						
S. aureus ATCC 29213	0.12-1	0.03										
		0.12			8	**8**	17			6	3	**26**
		0.25	41	152	159	**352**	3	3	41	142	117	**306**
		0.5		12	15	**27**				13	58	**71**
		1		1	2	**3**						**0**
		2								1		**1**

VIII. PROPOSED LABELLING

Expected quality control ranges and interpretive criteria are the same as those recommended by FDA and will be included in the package insert.

IX. CONCLUSION

The MTS™ Gepotidacin 0.016-256 µg/mL strip against Enterobacterales, *E. faecalis* and *S. saprophyticus* performs similar to broth microdilution methodology and supports a substantial equivalence decision.