July 31, 2018

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

Re: K181708
Trade/Device Name: MTS Plazomicin 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: June 27, 2018
Received: June 28, 2018

Dear Ms. 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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Steven R. Gitterman -S for

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number (if known)

K181708

Device Name

MTS™ Plazomicin 0.016-256 µg/mL

Indications for Use (Describe)

The Liofilchem® MTS™ (MIC Test Strip) 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. The MTS™ Plazomicin at concentrations of 0.016-256 µg/mL should be interpreted at 16-20 hours of incubation.

MTS™ PLZ can be used to determine the MIC of plazomicin against the microorganisms listed in the table below:

Plazomicin Activity According to the FDA Label

Clinical and *in vitro*	*in vitro* only
Enterobacter cloacae	*Citrobacter freundii*
Escherichia coli	*Citrobacter koseri*
Klebsiella pneumoniae	*Klebsiella (Enterobacter) aerogenes*
Proteus mirabilis	*Klebsiella oxytoca*
	Morganella morganii
	Proteus vulgaris
	Providencia stuartii
	Serratia marcescens

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.

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