November 19, 2018

Microgenics Corporation
Minoti Patel
Manager, Regulatory Affairs
46500 Kato Road
Fremont, California 94538

Re: DEN180030
Trade/Device Name: QMS Plazomicin Immunoassay
Regulation Number: 21 CFR 862.3460
Regulation Name: Plazomicin test system
Regulatory Class: Class II
Product Code: QDR
Dated: June 21, 2018
Received: June 25, 2018

Dear Minoti Patel:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the QMS Plazomicin Immunoassay, a prescription device with the following indications for use:

> The QMS Plazomicin Immunoassay is intended for the quantitative determination of plazomicin in human K2-EDTA plasma on automated clinical chemistry analyzers. The assay results obtained should only be used as an aid in the management of patients with complicated urinary tract infection (cUTI) receiving plazomicin therapy.
>
> The assay should only be used in conjunction with information available from clinical evaluations and other diagnostic procedures.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov. FDA concludes that this device should be classified into Class II. This order, therefore, classifies the QMS Plazomicin Immunoassay, and substantially equivalent devices of this generic type, into Class II under the generic name Plazomicin test system.

FDA identifies this generic type of device as:

> **Plazomicin test system**. A plazomicin test system is a device intended to measure plazomicin in human specimens. Measurements obtained by this device are used in monitoring levels of plazomicin to ensure appropriate therapy in patients with complicated urinary tract infection.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On June 25, 2018, FDA received your De Novo requesting classification of the QMS Plazomicin Immunoassay. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the QMS Plazomicin Immunoassay into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the QMS Plazomicin Immunoassay can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Identified Mitigations
Incorrect test results	General controls and special controls (1) and (2)
Incorrect interpretation of test results	General controls and special controls (1) and (2)

In combination with the general controls of the FD&C Act, the plazomicin test system must comply with the following special controls:

(1) Design verification and validation must include the following:
- (i) Precision study data that demonstrates clinically appropriate precision of the plazomicin test system, as determined by FDA. Precision studies must include a minimum of three samples containing different concentrations of plazomicin, including near medical decision points throughout the expected therapeutic range of plazomicin. Samples near the medical decision points must be clinical specimens collected from patients taking plazomicin.
- (ii) Method comparison data that demonstrates clinically appropriate accuracy of the plazomicin test system, as determined by FDA. Method comparison data must be collected at a minimum of three laboratory sites.
- (iii) Data from studies appropriate to demonstrate that the device is free from clinically significant interference from co-administered medications that are used in patients with complicated urinary tract infection, as determined by FDA.

(2) The device's 809.10 labeling must include a warning statement that reads: "The assay should only be used in conjunction with information available from clinical evaluations and other diagnostic procedures."

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the plazomicin test system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Eveline Arnold at 240-402-5334.

Sincerely,

Courtney H. Lias -S

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Director
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