September 27, 2018

Oxoid Limited (Part of Thermo Fisher Scientific)
Philip Brame
Regulatory Affairs Manager
Wade Road
Basingstoke, RG24 8PW Gb

Re: K181975
Trade/Device Name: Thermo Scientific Oxoid Meropenem/Vaborbactam Disc (30µg) MEV30
Regulation Number: 21 CFR 866.1620
Regulation Name: Antimicrobial susceptibility test disc
Regulatory Class: Class II
Product Code: JTN
Dated: July 23, 2018
Received: July 24, 2018

Dear Philip Brame:

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. 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 located 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.

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) 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 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)*
K181975

Device Name
Thermo Scientific Oxoid Meropenem/Vaborbactam Disc (30µg) MEV30

Indications for Use *(Describe)*
Thermo Scientific™ Oxoid™Antimicrobial Susceptibility Test (AST) Discs are used in the semi quantitative agar diffusion test method for in vitro susceptibility testing.

The Thermo Scientific Oxoid Meropenem/Vaborbactam Disc (30µg) MEV 30 can be used to determine susceptibility to Meropenem/Vaborbactam against the following bacteria for which Meropenem/Vaborbactam has been shown to be active both clinically and in vitro:

Escherichia coli
Klebsiella pneumoniae
Enterobacter cloacae species 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.

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510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Thermo Scientific Oxoid Meropenem/Vaborbactam Disc (30µg) MEV30 is provided below.

Device Common Name: Thermo Scientific Oxoid Meropenem/Vaborbactam Disc (30µg) MEV30

Device Trade Name: Thermo Scientific Oxoid Meropenem/Vaborbactam Disc (30µg) MEV30

Applicant: Oxoid Ltd

Contact: Philip Brame
Regulatory Affairs Manager Oxoid Ltd.
Wade Road Basingstoke
Hampshire RG24 8PW
United Kingdom
+44 (0)1256 694279
phil.brame@thermofisher.com

Date Prepared: 23-JULY-2018

Classification

Regulation: 21 CFR 866.1620

Panel: Microbiology

Product Code: JTN

Indications for Use:

Thermo Scientific Oxoid Antimicrobial Susceptibility Test (AST) Discs are used in the semi quantitative agar diffusion test method for in vitro susceptibility testing.

The Thermo Scientific Oxoid Meropenem /Vaborbactam Disc (30µ) MEV 30 can be used to determine susceptibility to Meropenem/Vaborbactam against the following bacteria for which Meropenem/Vaborbactam has been shown to be active both clinically and in vitro:

- *Escherichia coli*
- *Klebsiella pneumoniae*
- *Enterobacter cloacae species* complex.

Device Description:

Thermo Scientific Oxoid Meropenem/Vaborbactam Disc (30µg) MEV30 Antimicrobial Susceptibility Test Discs are 6mm. discs prepared by impregnating high quality absorbent paper with accurately determined amounts of Meropenem and Vaborbactam. The Disc is clearly marked on both sides with the code MEV30. The code designates the agent (Meropenem/Vaborbactam) and the drug content
(30µg).

Oxoid discs are supplied in cartridges containing 50 discs each, there are 5 cartridges per pack. Each cartridge is individually sealed together with a desiccant capsule in a foil covered see-through blister pack. Oxoid discs can be dispensed using an Oxoid Disc Dispenser.

Meropenem/Vaborbactam Disc (30µg) MEV30 Disc Content: Meropenem 20µg / Vaborbactam10µg.

Device Comparison:

***Table 5.1*: Similarities and differences between proposed and predicate devices.**

Similarities		
	Thermo Scientific Oxoid Meropenem/Vaborbactam Disc (30µg) MEV30	**Predicate Device** **HardyDisk Meropenem/Vaborbactam 20/10 µg (MEV30)** **K172621**
Intended Use	Oxoid Antimicrobial Susceptibility Test Discs are used in the semi quantitative agar diffusion test method for in vitro susceptibility testing.	Same
Antimicrobial Agent(s)	Meropenem/Vaborbactam	Same
Antimicrobial Agent Concentration	Meropenem 20µg/Vaborbactam 10µg	Same
Test Method	Semi quantitative agar diffusion test method using antimicrobial discs impregnated with an antimicrobial agent.	Same
Result Interpretation Method	Measurement of zone size	Same

Similarities		
	Thermo Scientific Oxoid Meropenem/Vaborbactam Disc (30µg) MEV30	**Predicate Device** **HardyDisk Meropenem/Vaborbactam 20/10 µg (MEV30)** **K172621**
Interpretation	Require the user to determine categorical interpretations (S/I/R) using the measured zone diameter against CLSI approved standards M02 and M100.	Same
Differences		
Product Name	Oxoid Meropenem/Vaborbactam Disc (30µg) MEV30	HardyDisk Meropenem/Vaborbactam 20/10 µg (MEV30)

Substantial Equivalence Conclusion:

Devices are substantially equivalent.

Performance Data:

The performance of the disc has been assessed through a comparative study with a predicate device (Hardy Meropenem Vaborbactam disk) on clinical and challenge isolates. The study also included QC and reproducibility studies. A summary of the results is detailed in section 20. The conclusion from the studies was that the disc performance was equivalent to the predicate device. A summary of the performance characteristics is presented here:

Performance Characteristics

The Oxoid Meropenem/Vaborbactam disc (30 µg, MEV30) was compared with a cleared disk (predicate) of the same antimicrobial, mass and concentration. The study included 300 clinical and 75 challenge isolates. The category agreement (CA) with the predicate was as follows:

Organism(s)	Total	CA (#)	CA (%)
Enterobacteriaceae [1, 2, 3]	375	372	99.2

[1] Including indicated organisms K. pneumoniae (184), Escherichia coli (121), and Enterobacter cloacae spp. Complex (35).

[2]The safety and efficacy of meropenem/vaborbactam in treating clinical infections due to Gram-Negative organisms other than Escherichia coli, Klebsiella pneumoniae, and Enterobacter cloacae species complex may or may not have been established in adequate and well-controlled clinical trials. The clinical significance of such susceptibility

information in those instances is unknown.
[3]The performance of Oxoid Meropenem/Vaborbactam disk (30 µg) MEV30 is unknown for Enterobacteriaceae with the following resistance mechanisms: overexpression of efflux pumps and/or lower expression of porins.

Product performance is in accordance with the recommendations of the manufacturer of the antibiotic.

Limitations
The ability of the Oxoid Meropenem/vaborbactam disc to detect resistance in species other than *K. pneumoniae* is unknown because an insufficient number of resistant strains were available at the time of comparative testing. If such a strain is observed, it should be submitted to a reference laboratory for further testing.

Table 5.2: **Susceptibility Interpretive Criteria for Meropenem/Vaborbactam Disc (30µg)**

Pathogen	**Disc Diffusion Zone Diameter (mm)**		
	S	**I**	**R**
Enterobacteriaceae	≥17	14-16	≤13

Abbreviations: S=Susceptible; I=intermediate; R=Resistant

Quality Control testing was completed in accordance with CLSI Performance Standards For Antimicrobial Disc Susceptibility Tests; Approved Standard - Twelfth Edition M02-A12 and Performance Standards for Antimicrobial Susceptibility Testing M100 – S27.

Quality Control testing was completed each day susceptibility testing is performed or weekly if satisfactory performance can be documented according to the CLSI Standard.

Control Zone Diameter Limits (mm) for organisms recommended to be tested are:

Table 5.3: **Acceptable Quality Control Ranges for Meropenem/Vaborbactam Disc (30µg) Susceptibility Testing**

Quality Control Organism	**Disc Diffusion Zone Diameter (mm)**
Klebsiella pneumoniae ATCC BAA-1705*	21-27
Klebsiella pneumoniae ATCC BAA-2814*	16-20
Escherichia coli ATCC 25922	31-37
Klebsiella pneumoniae ATCC 700603	29-35

ATCC = American Type Culture Collection
*KPC-producing *K. pneumoniae* included for the QC of vaborbactam activity