510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K261781

B Applicant

Thermo Fisher Scientific (Oxoid Ltd.)

C Proprietary and Established Names

Thermo Scientific Oxoid Cefepime/Zidebactam Disc (30/30 µg) FPZ60

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JTN	Class II	21 CFR 866.1620 - Antimicrobial Susceptibility Test Disc	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

In this Traditional 510(k) submission, Thermo Fisher Scientific (Oxoid Ltd.) seeks the following:

1. To obtain a substantial equivalence determination for the cefepime/zidebactam antimicrobial susceptibility test disk.
2. To establish a Pre-Determined Change Control Plan (PCCP) to address future revisions to device labeling in response to breakpoint changes that are recognized on the FDA STIC webpage.

B Measurand:

Cefepime/Zidebactam 30/30 µg

C Type of Test:

Antimicrobial Susceptibility Test Disks

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

Thermo Scientific Oxoid Antimicrobial Susceptibility Test Discs are used in the semi-quantitative agar diffusion test method for *in vitro* susceptibility testing. Used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having a microbial infection, these discs are intended to determine susceptibility against microorganisms for which specific drugs have been shown to be active both clinically and *in vitro*.

The Thermo Scientific Oxoid Cefepime/Zidebactam Disc (30/30 µg) FPZ60 is intended to determine susceptibility of Enterobacterales and *Pseudomonas aeruginosa* to cefepime/zidebactam, as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC). The Thermo Scientific Oxoid Cefepime/Zidebactam Disc (30/30 µg) FPZ60 demonstrated acceptable performance to determine susceptibility to cefepime/zidebactam against the following microorganisms:

Enterobacterales (*Citrobacter braakii*, *Citrobacter freundii*, *Citrobacter koseri*, *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Klebsiella variicola*, *Morganella morganii*, *Proteus mirabilis*, *Proteus vulgaris*, *Providencia rettgeri*, *Providencia stuartii*, *Serratia marcescens*)

Pseudomonas aeruginosa

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:

Thermo Scientific Oxoid Cefepime/Zidebactam Disc (30/30 µg) which is designated with the code FPZ60 is a high quality 6mm diameter white filter paper disk that is impregnated with 30 µg cefepime and 30 µg zidebactam. The disks are clearly marked on both sides with FPZ60, designating the agents and the drug contents. The disks are supplied in plastic cartridges containing 50 disks each. Thermo Scientific Oxoid Cefepime/Zidebactam Disc (30/30 µg) FPZ60 is intended to be used for *in vitro* agar diffusion susceptibility testing.

B Principle of Operation:

A suitable therapeutic agent for *in vitro* use can be determined using filter paper disks impregnated with specified concentrations of antimicrobial agents placed on the surface of a suitable test medium. Pure cultures of clinical isolates are inoculated onto the test medium, and the AST disk placed on the surface. The antibiotic within the disk diffuses into the agar. After incubation, the zones of inhibition around the disks are measured and compared against recognized zone diameter ranges for the specific antimicrobial agent/organism combination under test.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Thermo Scientific Oxoid Gepotidacin Disc (10 µg) GEP10

B Predicate 510(k) Number(s):

K251337

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device: K261781	Predicate: K251337
Device Trade Name	Thermo Scientific Oxoid Cefepime/Zidebactam Disc (30/30 µg) FPZ60	Thermo Scientific Oxoid Gepotidacin Disc (10 µg) GEP10
General Device Characteristic Similarities		
Intended Use	Antimicrobial Susceptibility Test Discs used in the semi-quantitative agar diffusion test method for *in vitro* susceptibility testing.	Same
Test Method	Antimicrobial susceptibility testing using paper disks impregnated with an antimicrobial agent.	Same
Methodology	Disk diffusion susceptibility test protocol requires the user to determine categorical interpretations (S/I/R) using the measured zone diameters.	Same
Inoculum	Prepared from pure isolated colonies to match the turbidity equivalent of a 0.5 McFarland.	Same
Inoculation Method	Dip a sterile swab into the prepared inoculums and streak an appropriate agar plate's surface three times. Add the	Same

Device & Predicate Device(s):	Device: K261781	Predicate: K251337
	disks impregnated with the antimicrobial agent to the surface of the plate. The temperature, atmospheric conditions, and duration of incubation are dependent on the organism tested.	
Reading Method	The user will interpret the zone diameters according to established interpretive criteria for the drug.	Same
General Device Characteristic Differences		
Antimicrobial Agent	Cefepime/Zidebactam	Gepotidacin
Concentration	30/30 µg	10 µg

Predetermined Change Control Plan (PCCP):

To support the implementation of changes to FDA-recognized susceptibility test interpretive criteria (i.e., breakpoints), this submission included a predetermined change control plan (PCCP) that was reviewed and accepted by FDA. This PCCP addresses future revisions to device labeling in response to breakpoint changes that are recognized on the FDA STIC webpage (FDA-Recognized Antimicrobial Susceptibility Test Interpretive Criteria). The PCCP outlined the specific procedures and acceptance criteria that Thermo Fisher Scientific (Oxoid Ltd.) intends to use to evaluate the Thermo Scientific Oxoid Cefepime/Zidebactam Disc (30/30 µg) FPZ60 when revised breakpoints for cefepime/zidebactam are published on the FDA STIC webpage. The PCCP included with the submission indicated that if specific criteria are met, Thermo Fisher Scientific (Oxoid Ltd.) will update the Thermo Scientific Oxoid Cefepime/Zidebactam Disc (30/30 µg) FPZ60 device label to include the new breakpoints.

VI Standards/Guidance Documents Referenced:

- CLSI M02-14th ed. *Performance Standards for Antimicrobial Disk Susceptibility Tests* (March 2024).
- CLSI M100-36th ed. *Performance Standards for Antimicrobial Susceptibility Testing* (January 2026).

VII Performance Characteristics (if/when applicable):

The premarket submission for Thermo Scientific Oxoid Cefepime/Zidebactam Disc (30/30 µg) FPZ60 included a letter dated December 4, 2025, indicating the right of reference to NDA 220787. Descriptive characteristics were sufficient for the Thermo Scientific Oxoid Cefepime/Zidebactam Disc (30/30 µg) FPZ60 disk based on data from microbiology disk studies evaluated by CDER which were used to generate the breakpoints identified by FDA on the susceptibility test interpretive criteria (STIC) webpage. In addition, CDER concurred with the

disk QC ranges that were established by CLSI. The disk data used to support this submission included data from testing organisms shown to be active *in vitro* and/or in clinical infections within the spectrum of activity of cefepime/zidebactam.

Data obtained from quality control, disk to MIC correlation, and reproducibility (from disk content optimization) studies were generated in accordance with the CDER Clinical/Antimicrobial guidance, *Microbiology Data for Systemic Antibacterial Drugs-Development, Analysis, and Presentation* to ensure precise, accurate, and reproducible results.

For this review, the interpretive criteria are applied to Enterobacterales and *Pseudomonas aeruginosa* according to the FDA STIC website. As required under 511A(2)(2)(B) of the Federal Food, Drug and Cosmetic Act, the following statement is included in the Precautions section of the Thermo Scientific Oxoid Cefepime/Zidebactam Disc (30/30 µg) FPZ60 package insert:

> *Per the FDA-Recognized Susceptibility Test Interpretive Criteria website, the safety and efficacy of antimicrobial drugs, for which antimicrobial susceptibility is tested by this AST device, may or may not have been established in adequate and well-controlled clinical trials for treating clinical infections due to microorganisms outside of those found in the indications and usage in the drug label. The clinical significance of susceptibility information in those instances is unknown. The approved labeling for specific antimicrobial drugs provides the uses for which the antimicrobial drug is approved.*

A Analytical Performance:

1. Precision/Reproducibility:

   Not applicable.

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

   Not applicable.

4. Detection Limit and Assay Reportable Range:

   Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Stability:
   A real-time stability study was conducted with the device stored in the storage conditions recommended in the package insert. Three lots of disks were tested throughout the 12-month claimed shelf life, and microbiological and chemical performance results were within the expected range, which is acceptable. Stability and storage information is provided in the package insert.

6. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable.

2. Matrix Comparison:

   Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Clinical Cut-Off:

   Not applicable.

4. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

D Expected Values/Reference Range:

Not applicable.

E Expected Values/Reference Range:

The FDA-recognized susceptibility interpretive criteria for cefepime/zidebactam are listed below in **Table 1**.

Table 1. FDA-Recognized Disk Diffusion Interpretive Criteria (zone diameter in mm) for Cefepime/Zidebactam

Organisms	Interpretive Criteria (mm)[a, b]		
	Susceptible (S)	Intermediate (I)	Resistant (R)
Enterobacterales	≥ 21	18 – 20	≤ 17
Pseudomonas aeruginosa	≥ 18	15 – 17	≤ 14

[a] FDA STIC Webpage, FDA-Recognized Antimicrobial Susceptibility Test Interpretive Criteria

[b] For disk diffusion, use paper disks impregnated with 30/30 mcg cefepime/zidebactam.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.