510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K251879

B Applicant

Liofilchem

C Proprietary and Established Names

Sulopenem SPM 2 µg

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, Liofilchem seeks the following:

1. Obtain a substantial equivalence determination for sulopenem antimicrobial susceptibility test disk.
2. 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:

Sulopenem 2 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:

Sulopenem SPM 2 µg is an *in vitro* semi-quantitative method for antimicrobial susceptibility of clinical isolates tested on agar media using overnight incubation.

The Sulopenem SPM 2 µg is intended to determine susceptibility of Enterobacterales to sulopenem, as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC). Sulopenem at concentrations of 2 µg should be interpreted at 16-18 hours of incubation.

The Sulopenem SPM 2 µg demonstrated acceptable performance with the following organisms:

Enterobacterales (*Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Citrobacter freundii*, *Citrobacter koseri*, *Enterobacter cloacae* complex, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Proteus vulgaris*, *Providencia alcalifaciens*, and *Providencia stuartii*)

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:

Sulopenem at concentrations of 2 µg is a high quality 6 mm diameter white filter paper disk that is impregnated with 2 µg sulopenem. The disks are clearly marked on both sides with SPM2, designating the agent and the drug content. The disks are supplied in plastic cartridges containing 50 disks each. Sulopenem SPM 2 µg is intended to be used for *in vitro* agar diffusion susceptibility testing.

B Principle of Operation:

The disks are applied to the surface of a culture medium inoculated with a pure colony suspension of the microorganisms under examination. The simultaneous growth of the bacteria and diffusion of the antimicrobials compounds forms a zone of inhibition of growth. After incubation, the plates are examined, the zone diameter around each disk are examined and compared with the standard inhibition zone diameter. The microorganisms are defined as being susceptible, intermediate or resistant to the tested antimicrobial agents.

V Substantial Equivalence Information:

A Predicate Device Name(s):

BD BBL Sensi-Disc Cefiderocol 30ug (FDC-30)

B Predicate 510(k) Number(s):

K221826

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device K251879	Predicate K221826
Device Trade Name	Sulopenem SPM 2 µg	BD BBL Sensi-Disc Cefiderocol 30µg (FDC-30)
General Device Characteristic Similarities		
Intended Use	Semi-quantitative susceptibility to antimicrobial agents against specified gram-negative organisms.	Semi-quantitative agar diffusion test method for *in vitro* susceptibility testing.
Test Method	Antimicrobial susceptibility testing using paper disks impregnated with an antimicrobial agent.	Same
Methodology	Kirby-Bauer 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 in Tryptic Soy Broth.	Same
Inoculum Method	Dip a sterile swab into the prepared inoculum and streak an appropriate agar plate's surface three times. Add the disks impregnated with the antimicrobial	Same

Device & Predicate Device(s):	Device K251879	Predicate K221826
	agent to the surface of the plate. The temperature, atmospheric conditions and duration of incubation is dependent on the organism tested.	
Reading Method	The user will interpret the zone diameters according to the established interpretive criteria for the drug.	Same
General Device Characteristic Differences		
Antimicrobial Agent	Sulopenem	Cefiderocol
Concentration	2 µg	30 µg

VI Standards/Guidance Documents Referenced:

- CLSI M02-14th ed. *Performance Standards for Antimicrobial Disk Susceptibility Tests* (March 2024).
- CLSI M100-35th ed. *Performance Standards for Antimicrobial Susceptibility Testing* (January 2025).

VII Performance Characteristics (if/when applicable):

The premarket submission for Sulopenem SPM 2 µg included a letter dated June 24, 2025, indicating the right of reference to NDA 213972. Descriptive characteristics were sufficient for the Sulopenem SPM 2 µg 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 with STIC-recognized breakpoints.

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 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 Sulopenem SPM 2 µg 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. Assay Reportable Range:

   Not applicable.

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

   Not applicable.

6. Detection Limit:

   Not applicable.

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

   Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The FDA-identified susceptibility interpretive criteria for sulopenem are listed below in **Table 1**.

Table 1. FDA-Identified Disk Diffusion Interpretive Criteria (zone diameter in mm) for Sulopenem

Organisms	Interpretive Criteria (mm)[a]		
	Susceptible (S)	Intermediate (I)	Resistant (R)
Enterobacterales	≥ 19	16 – 18	≤ 15

[a] FDA STIC Webpage

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.

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 (https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm). The PCCP outlined the specific procedures and acceptance criteria that Liofilchem intends to use to evaluate the Sulopenem SPM 2 µg when revised breakpoints for sulopenem are published on the FDA STIC webpage. The PCCP included with the submission indicated that if specific criteria are met, Liofilchem will update the Sulopenem SPM 2 µg disk device label to include the new breakpoints.