510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K242843

B Applicant

Thermo Fisher Scientific

C Proprietary and Established Names

The Sensititre 20-24 hour *Haemophilus influenzae/Streptococcus pneumoniae* MIC (HP) or Breakpoint Susceptibility System with Ceftobiprole in the dilution range of 0.008-16 µg/mL

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JWY	Class II	21 CFR 866.1640 - Antimicrobial Susceptibility Test Powder	MI - Microbiology
LRG	Class II	21 CFR 866.1640 - Antimicrobial susceptibility test powder	MI - Microbiology
LTT	Class II	21 CFR 866.1640 - Antimicrobial susceptibility test powder	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain substantial equivalence determination for The Sensititre 20-24 hour *Haemophilus influenzae/Streptococcus pneumoniae* MIC (HP) or Breakpoint Susceptibility System with Ceftobiprole in the dilution range of 0.008-16 µg/mL with FDA-recognized breakpoints for *Streptococcus pneumoniae* and *Streptococcus pyogenes*.

B Measurand:

Ceftobiprole in the dilution range of 0.008 to 16 µg/mL

C Type of Test:

Quantitative antimicrobial susceptibility test (AST) growth-based detection

III Intended Use/Indications for Use:

A Intended Use(s):
The Sensititre *Haemophilus influenzae/Streptococcus pneumoniae* plates are *in vitro* diagnostic products for clinical susceptibility testing of *Haemophilus influenzae*, *Streptococcus pneumoniae* and *Streptococcus* species.

B Indication(s) for Use:
The Sensititre 20-24 hour *Haemophilus influenzae/Streptococcus pneumoniae* MIC (HP) or Breakpoint Susceptibility System is an *in vitro* diagnostic product for clinical susceptibility testing of fastidious isolates.

This 510(k) is for ceftobiprole in the dilution range of 0.008-16 µg/mL for testing fastidious isolates on the Sensititre 20-24 hour *Haemophilus influenzae/Streptococcus pneumoniae* MIC (HP) or Breakpoint Susceptibility System. Testing is indicated for *Streptococcus pneumoniae* and *Streptococcus pyogenes*, as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC) webpage.

The Sensititre 20-24 hour *Haemophilus influenzae/Streptococcus pneumoniae* MIC (HP) or Breakpoint Susceptibility System with Ceftobiprole in the dilution range of 0.008-16 µg/mL demonstrated acceptable performance with the following organisms:

Streptococcus pneumoniae
Streptococcus pyogenes

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

The following limitations were applied to ceftobiprole testing in the appropriate sections of the device labeling that reference other drugs:

> *Studies of the following drugs were performed with the AIM Autoinoculator. The use of an alternative inoculation system has not been evaluated.*
>
> *Studies of the following drugs when tested with Streptococcus species were read using the ARIS HiQ/OptiRead and Vizion. The use of alternative read methods have not been evaluated.*

Due to the insufficient number of resistant *S. pneumoniae* and non-susceptible *S. pyogenes* isolates evaluated, the following limitation was applied to ceftobiprole testing in the appropriate section of the device labeling that references other drugs:

The ability of the Sensititre system to detect resistance or non-susceptibility to antimicrobics as shown below is unknown because an insufficient number of resistant or non-susceptible strains were available at the time of comparative testing. If such a strain is observed, it should be submitted to a reference laboratory.

D Special Instrument Requirements:

Sensititre AIM for device inoculation
Sensititre Vizion digital viewing device
Sensititre ARIS HiQ/OptiRead automated plate reader

IV Device/System Characteristics:

A Device Description:

The Sensititre 20-24 hour *Haemophilus influenzae/Streptococcus pneumoniae* (HP) MIC or Breakpoint Susceptibility System is an antimicrobial susceptibility test. Each plate is dosed with antimicrobial agents at appropriate dilutions. It is a micro-version of the classic broth dilution method and can provide both qualitative and quantitative susceptibility results. After inoculation, plates are sealed with an adhesive seal, incubated at 34-36°C for 20-24 hours and examined for bacterial growth.

B Principle of Operation:

The Sensititre 20-24 hour *Haemophilus influenzae/Streptococcus pneumoniae* (HP) MIC Susceptibility plates are multi-well plastic microtiter plates that contain doubled dilutions of antibacterial agents. Each plate includes antimicrobial agents at appropriate dilutions. Results can be read using the digital viewing device (Vizion) or by use of an automated plate reader (ARIS HiQ/OptiRead).

The Sensititre Vizion digital viewing device allows the panel image to be displayed on a touch screen directly from a video camera and allows the user to visually determine MIC results. The Sensititre OptiRead utilizes fluorescence technology to read the microbroth dilution plates after 20 to 24 hours incubation. The technology involves the detection of bacterial growth by monitoring the activity of specific surface enzymes produced by the test organism. Growth is determined by generating a fluorescent product from a fluorogenic substrate. The non-fluorescent substrate is prepared by conjugating a fluorescent compound to the specific enzyme substrates with a bond which prevents fluorescence. The enzymatic action of the bacterial surface enzymes on the bound non-fluorescent substrate cleaves the bond releasing fluorescence. The amount of fluorescence detected is directly related to the activity of bacterial growth. The MIC is determined by observing the lowest dilution of antimicrobial agent that inhibits growth of the organism. The non-fluorescent (fluorogenic) substrate can be added to the inoculum broth which is dispensed into the test plate at the same time as the test organism, or the plates can be prepared with the substrate already added to each micro-well.

Sensititre 20-24 hour *Haemophilus influenzae/Streptococcus pneumoniae* (HP) MIC plates can either be read automatically on an ARIS HiQ/OptiRead using fluorescence or by visual reading of growth on the Vizion digital viewing device.

V Substantial Equivalence Information:

A Predicate Device Name(s):
The Sensititre 20-24 hour *Haemophilus influenzae/Streptococcus pneumoniae* (HP) MIC or Breakpoint Susceptibility System with Imipenem in the dilution range of 0.015-4 µg/mL.

B Predicate 510(k) Number(s):
K240445

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device: K242843	Predicate: K240445
Device Trade Name	The Sensititre 20-24 hour *Haemophilus / Streptococcus pneumoniae* (HP) MIC or Breakpoint Susceptibility System with Ceftobiprole in the dilution range of 0.008-16 µg/mL	The Sensititre 20-24 hour *Haemophilus / Streptococcus pneumoniae* (HP) MIC or Breakpoint Susceptibility System with Imipenem in the dilution range of 0.015-4 µg/mL
General Device Characteristic Similarities		
Intended Use	The Sensititre *Haemophilus influenzae/Streptococcus pneumoniae* plates are *in vitro* diagnostic products for clinical susceptibility testing of *Haemophilus influenzae, Streptococcus pneumoniae* and *Streptococcus* species.	Same
Test Panel	Each 96 well plate is precision dosed with selected antimicrobial agents and substrate for the fluorescent reads, then dried. The bacterial suspension in the appropriate broth is used to rehydrate the plate.	Same
Incubation	20-24 hours	Same
Reading Method	Results can be read using fluorescence with the ARIS HiQ/OptiRead or by visual reading of growth with the Vizion.	Same
General Device Characteristic Differences		
Antibiotic and Dilution Range	Ceftobiprole 0.008-16 µg/mL	Imipenem 0.015-4 µg/mL
Test Organisms	*Streptococcus pneumoniae* and *Streptococcus pyogenes*	*Haemophilus influenzae* and *Streptococcus pneumoniae*

VI Standards/Guidance Documents Referenced:

CLSI M07, "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard - Eleventh Edition", (January 2018)

CLSI M100, "Performance Standards for Antimicrobial Susceptibility Testing; 33rd Edition", (March 2023)

Guidance for Industry and FDA: Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems, August 28, 2009

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

A reproducibility study of The Sensititre 20-24-hour *Haemophilus influenzae*/*Streptococcus pneumoniae* (HP) MIC or Breakpoint Susceptibility System with Ceftobiprole was performed at four sites using a panel of four *Streptococcus* isolates from indicated species (3 *S. pneumoniae* and 1 *S. pyogenes* isolates). In addition, 11 *Streptococcus* isolates (2 *S. agalactiae*, 2 *S. anginosus*, 2 *S. dysgalactiae*, 1 *S. mitis*, 2 *S. oralis*, 1 *S. parasanguinis*, and 1 *S. salivarius*) were tested that do not have FDA-recognized STIC breakpoints and are not intended for testing with the device. A supplementary reproducibility study was performed at three sites using a panel of six *Streptococcus* isolates from indicated species (3 *S. pneumoniae* and 3 *S. pyogenes* isolates).

All isolates were tested in triplicate over three days with each read method (i.e., automatically with the ARIS HiQ/OptiRead and visually with the Vizion). The Sensititre AIM Autoinoculator was used for Sensititre plate inoculation. The mode MIC value was determined, and the reproducibility was calculated based on MIC values falling within ±1 doubling dilution of the mode MIC value. The combined reproducibility study results for both the ARIS HiQ/OptiRead and Vizion read methods demonstrated acceptable performance of ≥95%.

In the supplementary study, there were 27 invalid results that did not produce adequate fluorescence by the ARIS HiQ/OptiRead. The majority of the invalid results occurred at one site from *S. pyogenes* isolates using a plate that was not fully inoculated. Repeat testing yielded 12 invalid results.

To address the high invalid rate for *S. pneumoniae* and *S. pyogenes*, the following general precaution statement was included in the device labeling:

> *The Autoread method is designed such that an autoread result is considered invalid when an isolate fails to produce adequate fluorescence in the positive control at the time of reading. If this occurs, it is recommended that the user manually confirm all results using a visual method. Prior to reporting any results, ensure that adequate*

growth is present in all control wells. If growth is not present in one or more control wells, the sample should be repeated.

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):

   The CLSI-recommended quality control (QC) strain *S. pneumoniae* ATCC 49619 was tested at four sites. The QC strain was tested a minimum of 20 times per site and read automatically with the ARIS HiQ/OptiRead and visually with the Vizion. The QC strain was also tested with the reference method. The results demonstrate that The Sensititre *Haemophilus influenzae/Streptococcus pneumoniae* (HP) MIC Susceptibility System with Ceftobiprole produced quality control results within the recommended range >95% of the time (**Table 1**).

   Table 1. Quality Control Results for *S. pneumoniae* with Ceftobiprole with the Reference Method, ARIS HiQ/OptiRead, and Vizion.

QC Organism	Expected Range (µg/mL)	Concentration (µg/mL)*	Reference	ARIS HiQ/OptiRead	Vizion
S. pneumoniae ATCC 49619	0.004-0.03 µg/mL	≤0.008	36	16	16
		0.015	54	77	77
		0.03	1	0	0
		≥0.06	0	1	1

* The CLSI quality control range for *S. pneumoniae* ATCC 49619 is 0.004-0.03 µg/mL. The Sensititre cleared formulary range for ceftobiprole is 0.008-16 µg/mL for fastidious organisms; as such, Quality Control MIC results of ≤0.008 µg/mL were considered acceptable.

Inoculum Density: Inoculum density checks were performed for all QC, reproducibility, challenge, and clinical isolates tested. Only results from cultures with appropriate inoculum densities were reported.

Purity Checks: Purity checks were performed each day for all QC, reproducibility, challenge, and clinical isolates tested. Only results from pure cultures were reported.

Growth Failures: There were no growth failures.

ARIS HiQ/OptiRead Invalid (No fluorescence): There was one invalid for *S. pyogenes* that did not produce adequate fluorescence by the ARIS HiQ/OptiRead.

6. Detection Limit:

Not applicable.

7. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Testing of The Sensititre *Haemophilus influenzae/Streptococcus pneumoniae* (HP) MIC Susceptibility System with Ceftobiprole was performed at three external sites and one internal site. Results were compared to those obtained with the CLSI broth microdilution reference method. Sensititre panels were inoculated using only the AIM Autoinoculator and results were read automatically by the ARIS HiQ/OptiRead and visually by the Vizion. Reference panels were inoculated according to recommendations in the M07 CLSI document and results were interpreted manually using a mirrored reader.

No inoculation system other than the AIM Autoinoculator was used in the comparative study. To address the inoculation method limitation, the following limitation was applied to ceftobiprole testing in the appropriate section of the device labeling that references other drugs:

Studies of the following drugs were performed with the AIM Autoinoculator. The use of an alternative inoculation system has not been evaluated.

No read method other than ARIS HiQ/OptiRead and Vizion was used in the comparative study. To address the read method limitation, the following limitation was applied to ceftobiprole testing in the appropriate section of the device labeling that references other drugs:

Studies of the following drugs when tested with Streptococcus species were read using the ARIS HiQ/OptiRead and Vizion. The use of alternative read methods have not been evaluated.

The testing conditions for the reference method consisted of the following:

- Media: per CLSI M07 guidelines for *Streptococcus* spp.
- Inoculum: Inoculated per CLSI M07 guidelines
- Incubation: 34-36°C in a non-CO_2 incubator for 20 to 24 hours.

Inoculation and incubation procedure for *Streptococcus* spp.

- Media: cation-adjusted Mueller Hinton broth with TES buffer (CAMHBT) and cation-adjusted Mueller Hinton broth with TES buffer and lysed horse blood (CAMHBT+LHB)
- Inoculum: A suspension approximating a 0.5 McFarland standard was prepared with *Streptococcus* spp. in 5 mL CAMHBT. A volume of 100 µL of the standardized

suspension was added to 11 mL of CAMHBT + LHB. Susceptibility panels were inoculated with 100 µL of the final organism suspension using the Sensititre AIM Autoinoculator.

- Incubation: 34-36°C in a non-CO_2 incubator for 20 to 24 hours.

A total of 299 *Streptococcus* clinical isolates comprised of 200 *S. pneumoniae* isolates and 99 *S. pyogenes* isolates as well as 70 challenge isolates comprised of 50 *S. pneumoniae* isolates and 20 *S. pyogenes* isolates were evaluated with the ARIS HiQ/OptiRead and the results are provided in **Table 2**.

For *S. pneumoniae* read using the ARIS HiQ/OptiRead, the combined clinical and challenge results (250 isolates) were acceptable at 99.6% and 98.4% for EA and CA, respectively. There were four minor errors, and no major or very major errors.

For *S. pyogenes* read using the ARIS HiQ/OptiRead, the combined clinical and challenge results (119 isolates) were acceptable at 92.4% and 100% for EA and CA, respectively. There were no potential major or very major errors. Errors are considered potential when no other category is defined other than "susceptible only".

Table 2. Ceftobiprole Performance of *S. pneumoniae* and *S. pyogenes* Read by ARIS HiQ/OptiRead

	Tot	EA N	EA %	Eval Tot	Eval EA N	Eval EA %	CA Tot	CA %	No. R/NS	No. S	min	maj	vmj
***S. pneumoniae* [≤ 0.5 (S), 0.1 (I), ≥2 (R)]**													
Clinical	200	200	100	86	86	100	198	99.0	0	200	2	0	0
Challenge	50	49	97.1	34	33	97.1	48	96.0	0	48	2	0	0
Total	250	249	99.6	120	119	99.2	246	98.4	0	248	4	0	0
***S. pyogenes* [≤ 0.5 (S)]**													
Clinical	99	92	92.9	10	3	30.0	99	100	0	99	NA	0	0
Challenge	20	18	90.0	4	2	50.0	20	100	0	20	NA	0	0
Total	119	110	92.4	14	5	35.7	119	100	0	119	NA	0	0

NA – Not applicable
EA – Essential Agreement
CA – Category Agreement
S – Susceptible
NS – Non-susceptible
EVAL – Evaluable MICs
R – Resistant
min – Minor Discrepancies
maj – Major Discrepancies
vmj – Very Major Discrepancies

Essential agreement (EA) occurs when the result of the reference method and that of the Sensititre panel are within plus or minus one serial two-fold dilution of the antibiotic. Evaluable results are those that are on scale for both the reference method and the Sensititre panel or those in which an off-scale result is at least two doubling dilutions from the on-scale result. Category agreement (CA) occurs when the interpretation of the result of the reference method agrees exactly with the interpretation of the Sensititre panel.

A total of 300 clinical isolates comprised of 200 *S. pneumoniae* isolates and 100 *S. pyogenes* isolates as well as 70 challenge isolates comprised of 50 *S. pneumoniae* isolates and 20 *S. pyogenes* isolates were evaluated with the Vizion and the results are provided in **Table 3**.

For *S. pneumoniae* read using the Vizion, the combined clinical and challenge results (250 isolates) were acceptable at 99.6% and 98.4% for EA and CA, respectively. There were four minor errors, and no major or very major errors.

For *S. pyogenes* read using the Vizion, the combined clinical and challenge results (120 isolates) were acceptable at 100% and 100% for EA and CA, respectively. There were no potential major or very major errors. Errors are considered potential when no other category is defined other than "susceptible only".

Table 3. Ceftobiprole Performance of *S. pneumoniae* and *S. pyogenes* Read by Vizion

	Tot	EA N	EA %	Eval Tot	Eval EA N	Eval EA %	CA Tot	CA %	No. R/NS	No. S	min	maj	vmj
***S. pneumoniae* [≤ 0.5 (S), 0.1 (I), ≥2 (R)]**													
Clinical	200	200	100	86	86	100	198	99.0	0	200	2	0	0
Challenge	50	49	98.0	35	34	97.1	48	96.0	0	48	2	0	0
Total	250	249	99.6	121	120	99.2	146	98.4	0	248	4	0	0
***S. pyogenes* [≤ 0.5 (S)]**													
Clinical	100	100	100	3	3	100	100	100	0	100	NA	0	0
Challenge	20	20	100	2	2	100	20	100	0	20	NA	0	0
Total	120	120	100	5	5	100	120	100	0	120	NA	0	0

NA – Not applicable
EA – Essential Agreement
CA – Category Agreement
S – Susceptible
NS – Non-susceptible
EVAL – Evaluable MICs
R – Resistant
min – Minor Discrepancies
maj – Major Discrepancies
vmj – Very Major Discrepancies

Essential agreement (EA) occurs when the result of the reference method and that of the Sensititre panel are within plus or minus one serial two-fold dilution of the antibiotic. Evaluable results are those that are on scale for both the reference method and the Sensititre panel or those in which an off-scale result is at least two doubling dilutions from the on-scale result. Category agreement (CA) occurs when the interpretation of the result of the reference method agrees exactly with the interpretation of the Sensititre panel.

Due to the insufficient number of resistant *S. pneumoniae* and non-susceptible *S. pyogenes* isolates evaluated, the following limitation was applied to ceftobiprole testing in the appropriate section of the device labeling that references other drugs:

> *The ability of the Sensititre system to detect resistance or non-susceptibility to antimicrobics as shown below is unknown because an insufficient number of resistant or non-susceptible strains were available at the time of comparative testing. If such a strain is observed, it should be submitted to a reference laboratory.*

MIC Trending

A trending analysis was conducted using the combined data (clinical and challenge) obtained for both the ARIS HiQ/OptiRead and the Vizion for *S. pneumoniae* and *S. pyogenes*. This trending calculation takes into account MIC values that are determined to be one or more doubling dilutions lower or higher than the reference method irrespective of whether the device MIC values are on-scale or not. Results that are not clearly at least one dilution lower at least one dilution higher or in exact agreement with the CLSI reference method are not considered in the trending analysis.

Species for which the difference between the percentage of isolates with higher vs. lower readings was > 30% and for which the confidence interval was determined to be statistically

significant were considered to show evidence of trending. Trending that shows higher or lower MIC values compared to the reference is addressed in the labeling.

Evaluation of results for *S. pneumoniae* and *S. pyogenes* with ceftobiprole using the ARIS HiQ/OptiRead and Vizion are summarized in **Table 4**. A trend toward higher MIC values was observed for *S. pneumoniae* and *S. pyogenes* using ARIS HiQ/OptiRead when compared to the CLSI broth microdilution reference method. A trend toward higher MIC values was observed for *S. pneumoniae* and *S. pyogenes* using Vizion when compared to the CLSI broth microdilution reference method.

To address the MIC trending, the following footnotes were included in the performance table in the device labeling:

For ARIS HiQ/OptiRead:

Sensititre Ceftobiprole MIC values tended to be in exact agreement or at least one doubling dilution higher when testing S. pneumoniae and S. pyogenes with the ARIS HiQ/OptiRead *method compared to the CLSI broth microdilution reference method*.

For Vizion:

Sensititre Ceftobiprole MIC values tended to be in exact agreement or at least one doubling dilution higher when testing S. pneumoniae and S. pyogenes with the Vizion compared to the CLSI broth microdilution reference method.

Table 4. Ceftobiprole Trending Analysis for *S. pneumoniae* and *S. pyogenes* with ARIS HiQ/OptiRead and Vizion

Read Method	Organism	Total Evaluable for Trending	≥ 1 Dilution Lower No. (%)	Exact No. (%)	≥ 1 Dilution Higher No. (%)	Percent Difference (95% CI)	Trending Noted
ARIS HiQ/ OptiRead	*S. pneumoniae*	168	9 (5.4%)	79 (47.0%)	80 (47.6%)	42.3% (33.6% to 50.2%)	Yes, High
	S. pyogenes	28	1 (3.6%)	3 (10.7%)	24 (85.7%)	82.1% (59.9% to 91.2%)	Yes, High
Vizion	*S. pneumoniae*	170	7 (4.1%)	80 (47.1%)	83 (48.8%)	44.7% (36.2% to 52.5%)	Yes, High
	S. pyogenes	22	2 (9.1%)	2 (9.1%)	18 (81.8%)	72.7% (45.1% to 85.4%)	Yes, High

Testing/Reporting MICs for Non-indicated Species.

For this review, the interpretive criteria are applied to the organisms/organism groups 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 Warnings and Precautions section of the device labeling to address testing and reporting of non-indicated species:

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.

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:

Table 5. FDA-Recognized Interpretive Criteria for Ceftobiprole

Organisms	Minimum Inhibitory Concentrations (µg/mL)[a]		
	Susceptible	Intermediate	Resistant
Streptococcus pneumoniae	≤0.5	1	≥2
Streptococcus pyogenes	≤0.5	-	-

[a]According to the 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 incorporated by reference a breakpoint change protocol that was reviewed and accepted by FDA in submission K231994 cleared on August 25, 2023. This referenced protocol addresses future revisions to device labeling in response to

breakpoint changes that are recognized on the FDA STIC webpage (https://www.fda.gov/drugs/development-resources/fda-recognized-antimicrobial-susceptibility-test-interpretive-criteria). The referenced protocol outlined the specific procedures and acceptance criteria that Thermo Fisher Scientific intends to use to evaluate The Sensititre 20-24 hour *Haemophilus influenzae/Streptococcus pneumoniae* MIC (HP) or Breakpoint Susceptibility System with Ceftobiprole when revised breakpoints for ceftobiprole are published on the FDA STIC webpage. The breakpoint change protocol included with the submission indicated that if specific criteria are met, Thermo Fisher Scientific will update the ceftobiprole device label to include (1) the new breakpoints, (2) an updated performance section after re-evaluation of data in this premarket notification with the new breakpoints, and (3) any new limitations as determined by their evaluation.