DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*

K182797

Device Name

Sensititre 18 – 24 hour MIC or Breakpoint Susceptibility System with Eravacycline in the dilution range of 0.008 – 16 µg/mL

Indications for Use *(Describe)*

The Sensititre 18 – 24 hour MIC or Breakpoint Susceptibility System is an *in vitro* diagnostic product for clinical susceptibility testing of non-fastidious isolates.

This 510(k) is for Eravacycline in the dilution range 0.008 – 16 µg/mL for non-fastidious gram-negative and gram-positive organisms on the Senstitire 18 – 24 hour MIC panel.

Eravacycline has been shown to be active both clinically and *in vitro* against the following organisms according to the FDA drug label:

Gram-negative bacteria
- *Escherichia coli*
- *Klebsiella oxytoca*
- *Klebsiella pneumoniae*
- *Citrobacter freundii*
- *Enterobacter cloacae*

Gram-positive bacteria
- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Staphylococcus aureus*

The following *in vitro* data are available, but their clinical significance is unknown:

Gram-nagative bacteria:
- *Citrobacter koseri*
- *Klebsiella (Enterobacter) aerogenes*

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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