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)*

K183140

Device Name

MTS™ Tetracycline 0.016 - 256 µg/mL

Indications for Use *(Describe)*

The MTS™ Tetracycline 0.016 - 256 µg/mL is a quantitative method intended for the in vitro determination of antimicrobial susceptibility of bacteria. MTS™ consists of specialized paper impregnated with a pre-defined concentration gradient of an antimicrobial agent, which is used to determine the minimum inhibitory concentration (MIC) in µg/mL of antimicrobial agents against bacteria as tested on agar media using overnight incubation and manual reading procedures.

The MTS™ Tetracycline at concentrations of 0.016 - 256 µg/mL should be interpreted at 16-20 hours of incubation.

Tetracycline has been shown to be active both clinically and in vitro against these bacterial species according to the FDA drug approved label:

Staphylococcus aureus
Acinetobacter baumannii
Escherichia coli
Klebsiella aerogenes
Klebsiella oxytoca
Klebsiella pneumoniae

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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