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)*

K183298

Device Name

HardyDisk™ AST Omadacycline 30µg (OMC30)

Indications for Use *(Describe)*

HardyDisk™ AST Disks are used for semi-quantitative in vitro susceptibility testing by the agar diffusion test procedure (Kirby-Bauer) of rapidly growing and certain fastidious bacterial pathogens. Standardized methods for agar diffusion testing have been described for *Enterobacteriaceae*, *Staphylococcus* spp., *Pseudomonas* spp., *Acinetobacter* spp., *Listeria monocytogenes*, *Enterococcus* spp., and by modified procedures, *Haemophilus* spp., *Neisseria gonorrhoeae*, *N. meningitidis* and *Streptococcus* spp., including *Streptococcus pneumoniae*.

Use of HardyDisk™ AST Omadacycline 30µg (OMC30) for in vitro agar diffusion susceptibility testing is indicated when there is the need to determine the susceptibility of bacteria to Omadacycline.

HardyDisk™ AST Omadacycline at concentration 30µg can be used to determine the zone diameter (mm) of Omadacycline against the following bacteria for which Omadacycline has been shown to be active both clinically and in vitro:

Staphylococcus aureus (methicillin-susceptible and -resistant isolates)
Staphylococcus lugdunensis
Enterococcus faecalis
*Streptococcus anginosus group (*includes *S. anginosus*, *S. intermedius*, and *S. constellatus)*
Streptococcus pneumoniae
Streptococcus pyogenes
Haemophilus influenzae
Haemophilus parainfluenzae
Enterobacter cloacae
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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