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)*

K181700

Device Name

HardyDisk™ AST Plazomicin 30µg (PLZ30)

Indications for Use *(Describe)*

Use of HardyDisk™ AST Plazomicin 30µg (PLZ30) for *in vitro* agar diffusion susceptibility testing is indicated when there is the need to determine the susceptibility of bacteria to Plazomicin.

Plazomicin has been shown to be active against susceptible isolates of the following bacteria, both *in vitro* and in clinical infections: *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, and *Enterobacter cloacae*.

Plazomicin has been shown to be active in vitro against susceptible isolates of the following bacteria: Citrobacter freundii, *Citrobacter koseri*, *Klebsiella aerogenes* (*Enterobacter aerogenes*), *Klebsiella oxytoca*, *Morganella morganii*, *Proteus vulgaris*, *Providencia stuartii* and *Serratia marcescens*.

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*.

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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