

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

K093807

B. Purpose for Submission:

To obtain a substantial equivalent determination for the Telavancin 30µg, Hardy Diagnostics™ Sensi-Disc™.

C. Measurand:

Susceptibility to Telavancin 30µg

D. Type of Test:

Semi-quantitative Antimicrobial Susceptibility Test Disc

E. Applicant:

Hardy Diagnostics

F. Proprietary and Established Names:

Hardy Disk µg Telavancin, 30µg

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JTN	II	866.1620	83 Microbiology

H. Intended Use:

1. Intended use(s):

Hardy Disk™ 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. meningitides and *Streptococcus* spp., including *Streptococcus pneumoniae*.

2. Indication(s) for use:

Use of Hardy Disk™ Telavancin 30µg for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to telavancin. The concentration of telavancin 30µg has been shown to be active against most isolates of the following microorganisms both *in vitro* and in clinical infections.

Methicillin-resistant *Staphylococci*
Streptococci
Vancomycin- susceptible *Enterococci*

3. Special conditions for use statement(s):

For prescription use only.

4. Special instrument requirements:

None

I. Device Description:

The Telavancin 30µg Hardy Disk™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk utilizes 6-mm disks prepared by impregnating absorbent paper with a known concentration. Each telavancin disk is marked on both sides with the agent (TLV) and drug content. (1) Cartridges each contain 50 impregnated disks that are packed as either a single cartridge in a single box, or in a package containing five cartridges.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Tigecycline 15µg, Hardy Disk™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk.

2. Predicate 510(k) number(s):

K062245

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	An <i>in vitro</i> diagnostic product for clinical susceptibility testing of aerobic gram positive and gram negative bacteria	same
Inoculum	Prepared from pure isolated colonies using the direct inoculation method or growth method	same
Inoculation method	Directly equated to a 0.5 McFarland turbidity standard	same

Difference		
Item	Device	Predicate
Antibiotic	Telavancin	Tigecycline
Concentration	30µg	15µg

K. Standard/Guidance Document Referenced (if applicable):

CLSI M2-A9 "Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard." CLSI M100-S 16, "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard". The Center for Drug Evaluation and Review (CDER) pharmaceutical approved package insert, developed during clinical trial studies, was used for Interpretive Criteria and Quality Control (QC) Expected Ranges.

L. Test Principle:

HardyDisk™ utilizes dried filter paper disks impregnated with known concentrations of antimicrobial agents that are placed onto the test medium surface. The standard method of testing is the Kirby-Bauer method. The recommended test medium is caution-adjusted Mueller-Hinton agar supplemented with the appropriate concentration of calcium. Four to five colonies are transferred to 5 ml of a suitable broth medium. The broth is incubated at 35-37⁰ C for 2 to 8 hours until a light to moderate turbidity develops. Alternately, a direct broth or saline suspension of colonies may be prepared from an 18-24 hour agar plate culture. The final inoculum density should be equivalent to a 0.5 McFarland turbidity standard. The inoculum density may also be standardized

photometrically. Within 15 minutes of inoculum preparation, the Mueller-Hinton agar is streaked to obtain an even inoculation. Disks are aseptically placed onto the agar surface with a disk dispenser or sterile forceps to ensure contact with the test surface. Plates are incubated in an ambient air incubator at 35-37⁰ C. fastidious organisms (*Streptococcus species*) are tested using appropriate media incubated in a CO₂ enriched atmosphere, as recommended in the CLSI M7 Approved Standard document. After incubation the media is examined, and zones of inhibition around the disks are measured and compared against recognized zone size ranges for the antimicrobial agent being tested.

M. Performance Characteristics (if/when applicable):

(Descriptive characteristics were sufficient for this disk, because the drug studies, evaluated by CDER at the time of telavancin approval, evaluated 1794 patients with skin and skin structure infections This data was used to generate the Interpretive Criteria and QC Expected Ranges.

1. Analytical performance:

a. *Precision/Reproducibility:*

b. *Linearity/assay reportable range:*

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Q.C. isolates and the Expected Ranges are the same as recommended by the FDA/CDER in the approved pharmaceutical package insert.

d. *Detection limit:*

e. *Analytical specificity:*

f. *Assay cut-off:*

2. Comparison studies:

Not required for Antimicrobial Susceptibility Discs.

a. *Method comparison with predicate device:*

b. *Matrix comparison:*

3. Clinical studies:

Not required for Antimicrobial Susceptibility Discs.

a. *Clinical Sensitivity:*

b. *Clinical specificity:*

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Staphylococcus aureus $\geq 15\text{mm}$ (S)*

Enterococcus faecalis (vancomycin-susceptible isolates only) $\geq 15\text{mm}$ (S)*

Streptococcus species other than *S. pneumoniae* $\geq 15\text{mm}$ (S)*

* The current absence of resistant isolates precludes defining any results other than “Susceptible”. Isolates yielding MIC or disk diffusion results suggestive of “Nonsusceptible” should be subjected to additional testing.

The Interpretive Criteria, Q.C. isolates and the Expected Ranges are the same as recommended by the FDA/CDER in the approved pharmaceutical package insert. All values will be included in the device package insert.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809. 10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.