# 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
# DECISION SUMMARY
ASSAY ONLY

## I Background Information:

### A 510(k) Number

K260282

### B Applicant

bioMérieux, Inc.

### C Proprietary and Established Names

VITEK 2 AST-*Streptococcus* Inducible Clindamycin Resistance

### D Regulatory Information

| Product Code(s) | Classification | Regulation Section | Panel |
|---|---|---|---|
| LON | Class II | 21 CFR 866.1645 - Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System | MI - Microbiology |
| LTT | Class II | 21 CFR 866.1640 - Antimicrobial susceptibility test powder | MI - Microbiology |
| LTW | Class II | 21 CFR 866.1640 - Antimicrobial susceptibility test powder | MI - Microbiology |

## II Submission/Device Overview:

### A Purpose for Submission:

To obtain a substantial equivalence determination for the VITEK 2 AST-*Streptococcus* Inducible Clindamycin Resistance device for testing *Streptococcus pneumoniae* and *Streptococcus* spp. β-hemolytic group on the VITEK 2, VITEK 2 Compact, and VITEK COMPACT PRO Antimicrobial Susceptibility Test (AST) Systems.

### B Measurand:

Clindamycin 0.5 µg/mL
Clindamycin/Erythromycin 0.25/0.5 µg/mL

### C Type of Test:

Automated qualitative antimicrobial susceptibility test

## III Intended Use/Indications for Use:

### A Intended Use(s):

See Indications for Use below.

### B Indication(s) for Use:

VITEK 2 AST *Streptococcus* Inducible Clindamycin Resistance is designed for antimicrobial susceptibility testing of *Streptococcus* species and is intended for use with the VITEK 2 Systems as a laboratory aid in the determination of in vitro susceptibility to antimicrobial agents.

VITEK 2 AST *Streptococcus* Inducible Clindamycin Resistance is a qualitative test. Testing is indicated for *Streptococcus pneumoniae* and *Streptococcus* spp. β-hemolytic group.

VITEK 2 AST *Streptococcus* Inducible Clindamycin Resistance has demonstrated acceptable performance with the following organisms:
*Streptococcus pneumoniae*
*Streptococcus* spp. β-hemolytic group (*Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus canis, Streptococcus dysgalactiae equisimilis, Streptococcus equi zooepidemicus*)

The VITEK 2 *Streptococcus* Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Streptococcus pneumoniae*, beta-hemolytic *Streptococcus*, and Viridans *Streptococcus* to antimicrobial agents when used as instructed.

### C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:
Inducible Clindamycin Resistance (icr02n): *Streptococcus pneumoniae*

Perform an alternative method of testing prior to reporting of results when a Positive (+) result is obtained with the following antibiotic/organism combination(s):
Inducible Clindamycin Resistance (icr02n): *Streptococcus dysgalactiae equisimilis*

### D Special Instrument Requirements:

VITEK 2 Systems (i.e., VITEK 2, VITEK 2 Compact, and VITEK COMPACT PRO), Software version 10.1 or newer

## IV Device/System Characteristics:

### A Device Description:

The VITEK 2 AST card is a miniaturized, abbreviated and automated version of the doubling dilution technique for determining the minimum inhibitory concentration (MIC). Each VITEK 2 AST card contains 64 wells. A control well which contains only nutrient medium is resident on all cards. The remaining wells contain premeasured portions of antimicrobials combined with the nutrient media. The isolate to be tested is diluted to a standardized concentration with 0.45% to 0.50% saline before being used to rehydrate the antimicrobial medium within the card.

VITEK 2 AST cards are intended to be used with VITEK 2 System instruments (VITEK 2, VITEK 2 Compact, and VITEK COMPACT PRO). The VITEK 2 System instruments are fully automated instruments that integrate sample preparation, incubation, and optical measurement for microbial identification and antimicrobial susceptibility testing (AST).

The VITEK 2 System will automatically (or allow operator to manually) dilute the organism suspension to prepare an inoculum for susceptibility cards. Then, the VITEK 2 will fill, seal and place the card into the incubator/reader. The VITEK 2 Compact and VITEK COMPACT PRO have a manual filling, sealing, and loading operation. The VITEK 2 Systems monitor the growth of each well in the card over a defined period of time. The analysis program determines when a well demonstrates growth based on attenuation of light measured by an optical scanner. The data are used to determine the MIC values for the antimicrobial agent. At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antimicrobial contained on the card.

VITEK 2 AST- *Streptococcus* Inducible Clindamycin Resistance has the following concentrations in the card: clindamycin 0.5 µg/mL, clindamycin/erythromycin at 0.25/0.5 (equivalent standard method concentration by efficacy in µg/mL). Results of the VITEK 2 AST- *Streptococcus* Inducible Clindamycin Resistance are reported as Positive (inducible resistance to clindamycin) or Negative (no inducible resistance to clindamycin).

### B Principle of Operation:

The VITEK 2 AST cards use an abbreviated doubling dilution series of antimicrobial to establish the MIC. Each VITEK 2 AST card contains 64 wells—one “growth” control well contains nutrient medium only, and the remaining wells contain premeasured antimicrobials in nutrient media.

The VITEK 2 System instruments (VITEK 2, VITEK 2 Compact, and VITEK COMPACT PRO) utilize automated growth-based detection using attenuation of light measured by an optical scanner. The optics in the VITEK 2 Systems use visible light to directly measure organism growth within each of the 64 micro-wells. Transmittance optics are based on an initial light reading of a well before significant growth has begun. Every 15 minutes throughout the incubation cycle (defined period of time based on the VITEK 2 AST card), light transmittance readings of each well determine organism growth by the amount of light that is prevented from passing through the well. At the completion of the incubation period, the MIC values and their

associated interpretive category results for each antimicrobial on the test card are displayed in an automatically generated report.

## V Substantial Equivalence Information:

### A Predicate Device Name(s):

VITEK 2 *Streptococcus* Inducible Clindamycin Resistance

### B Predicate 510(k) Number(s):

K111909

### C Comparison with Predicate(s):

| **Device & Predicate Device(s):** | **Device: K260282** | **Predicate: K111909** |
|---|---|---|
| Device Trade Name | VITEK 2 AST-*Streptococcus* Inducible Clindamycin Resistance | VITEK 2 *Streptococcus* Inducible Clindamycin Resistance |
| **General Device Characteristic Similarities** | | |
| Indications For Use/Intended Use | VITEK 2 AST *Streptococcus* Inducible Clindamycin Resistance is designed for antimicrobial susceptibility testing of *Streptococcus* species and is intended for use with the VITEK 2 Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents.<br><br>VITEK 2 AST *Streptococcus* Inducible Clindamycin Resistance is a qualitative test. Testing is indicated for *Streptococcus pneumoniae* and *Streptococcus* spp. β-hemolytic group.<br><br>VITEK 2 AST *Streptococcus* Inducible Clindamycin Resistance has demonstrated acceptable performance with the following organisms: *Streptococcus pneumoniae Streptococcus* spp. β-hemolytic group (*Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus canis,* | VITEK 2 *Streptococcus* Inducible Clindamycin Resistance is designed for antimicrobial susceptibility testing of *Streptococcus agalactiae* and *Staphylococcus pyogenes*.<br><br>VITEK 2 AST-ST Inducible Clindamycin Resistance is a qualitative test. It is intended for use with the VITEK 2 and VITEK 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents.<br><br>The VITEK 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK 2 Systems for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic Gram-negative bacilli, *Staphylococcus* spp., *Enterococcus* spp., *Streptococcus* spp. and yeast. |

| Device & Predicate Device(s): | Device: K260282 | Predicate: K111909 |
|---|---|---|
| | *Streptococcus dysgalactiae equisimilis, Streptococcus equi zooepidemicus*)<br><br>The VITEK 2 *Streptococcus* Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Streptococcus pneumoniae*, beta-hemolytic *Streptococcus*, and Viridans *Streptococcus* to antimicrobial agents when used as instructed. | |
| Test Methodology | Automated qualitative antimicrobial susceptibility test for use with the VITEK 2 Systems to determine the *in vitro* susceptibility of *Streptococcus* species. | Same |
| Inoculum | Saline suspension of organism | Same |
| Analysis Algorithm | Discriminant Analysis | Same |
| Test Card | VITEK 2 *Streptococcus* Susceptibility Test Card | Same |
| Antimicrobial Agents and Concentrations | Clindamycin 0.5 µg/mL<br>Clindamycin/Erythromycin 0.25/0.5 µg/mL | Same |
| **General Device Characteristic Differences** | | |
| Instrument | VITEK 2, VITEK 2 Compact, and VITEK COMPACT PRO Systems | VITEK 2 and VITEK 2 Compact Systems |
| Base Broth | Modified ST1 | ST4 |
| Tested Species | *Streptococcus pneumoniae*<br><br>*Streptococcus* spp. β-hemolytic group (*Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus canis, Streptococcus dysgalactiae equisimilis, Streptococcus equi zooepidemicus*) | *Streptococcus agalactiae*<br>*Streptococcus pyogenes* |

**Predetermined Change Control Plan (PCCP):**
To support the implementation of changes to FDA-recognized susceptibility test interpretive criteria (i.e., breakpoints), this submission included a predetermined change control plan (PCCP) with a breakpoint change protocol that was reviewed and accepted by FDA in submission

K250274 cleared on April 30, 2025. This protocol addresses future revisions to device labeling in response to breakpoint changes that are recognized on the FDA STIC webpage (https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm). The protocol outlined the specific procedures and acceptance criteria that bioMérieux intends to use to evaluate the VITEK 2 AST-*Streptococcus* Inducible Clindamycin Resistance when revised breakpoints for clindamycin are published on the FDA STIC webpage. The breakpoint change protocol included with the submission indicated that if specific criteria are met, bioMérieux will update the VITEK 2 AST-*Streptococcus* Inducible Clindamycin Resistance label to include (1) the new breakpoints, (2) an updated performance section after re-evaluation of data in this premarket notification with the new breakpoints, and (3) any new limitations as determined by their evaluation.

## VI Standards/Guidance Documents Referenced:

- Guidance for Industry and FDA - Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems – August 28, 2009.
- CLSI M07 12th Edition, Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically (May 2024)
- CLSI M100 35th ed. Performance Standards for Antimicrobial Susceptibility Testing (January 2025)

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

1. Precision/Reproducibility:

Reproducibility testing for the VITEK 2 AST-*Streptococcus* Inducible Clindamycin Resistance was conducted at three external sites using a panel of five *Streptococcus pneumoniae* isolates negative for inducible clindamycin resistance (ICR), three *Streptococcus agalactiae* isolates positive for ICR, and two *Streptococcus pyogenes* isolates positive for ICR consistent with the device indications for use. Each isolate was tested in triplicate, using separate inoculum for each, and tested over three days for a total of 270 data points. The inocula were prepared using both the auto-dilution and manual dilution methods for testing with the VITEK 2 and the manual dilution method for testing with the VITEK 2 Compact.

The COMPACT PRO did not obtain premarket clearance until after the closure of the external study sites; therefore, reproducibility for the COMPACT PRO was assessed with separate inocula prepared from 10 isolates and evaluated at one internal site with three instruments and three operators for a total of 270 data points. Due to the similarities between the two Compact systems, the VITEK 2 Compact reproducibility performance was additionally leveraged to support the VITEK COMPACT PRO. Taken together, this was considered acceptable.

As a qualitative test, results were evaluated by comparing the VITEK 2 System instruments results to the expected result for each isolate. The reproducibility performance is shown in

**Table 1**. The reproducibility was 100% across all VITEK 2 instruments and dilution methods.

**Table 1**. **Reproducibility Performance of VITEK 2 AST-*Streptococcus* Inducible Clindamycin Resistance**

| VITEK 2 | | VITEK 2 Compact | VITEK COMPACT PRO |
|---|---|---|---|
| **Auto-Dilution** | **Manual Dilution** | **Manual Dilution** | **Manual Dilution** |
| 100% | 100% | 100% | 100% |

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

   Not applicable.

4. Detection Limit and Assay Reportable Range:

   Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   **Quality Control (QC) Testing:**
   The CLSI recommended QC strains *Staphylococcus aureus* ATCC BAA-977 and *Streptococcus pneumoniae* ATCC 49619 were tested a sufficient number of times (i.e., at least 20/site) at each testing site using the VITEK 2 AST-*Streptococcus* Inducible Clindamycin Resistance and D-test disk diffusion standard method. Both the automatic dilution and manual dilution methods were used for the VITEK 2 and the manual dilution method was used for the VITEK 2 Compact and VITEK COMPACT PRO. The results are summarized in **Table 2** below. Both the auto-dilution and manual dilution methods for VITEK 2 and the manual dilution methods for VITEK 2 Compact and VITEK COMPACT PRO QC results were within the expected range 100% of the time.

**Table 2. Quality Control Results for VITEK 2 AST-*Streptococcus* Inducible Clindamycin Resistance**

| Inducible Clindamycin Resistance | VITEK 2 | | | | VITEK 2 Compact | | VITEK 2 COMPACT PRO | |
|---|---|---|---|---|---|---|---|---|
| | Auto-Dilution | | Manual Dilution | | Manual Dilution | | Manual Dilution | |
| QC Organisms | D-test | VITEK | D-test | VITEK | D-test | VITEK | D-test | VIEK |
| *S. aureus* ATCC BAA-977 Expected Result: POS | 119/119 (100%) | 119/119 (100%) | 65/65 (100%) | 65/65 (100%) | 65/65 (100%) | 65/65 (100%) | 22/22 (100%) | 22/22 (100%) |
| *S. pneumoniae* ATCC 49619 Expected Result: NEG | 191/191 (100%) | 191/191 (100%) | 90/90 (100%) | 90/90 (100%) | 90/90 (100%) | 90/90 (100%) | 22/22 (100%) | 22/22 (100%) |

One ancillary QC organism, *Staphylococcus aureus* ATCC BAA-976, was tested throughout comparative testing by the D-test disk diffusion standard method only to ensure further quality control of the disk diffusion panels. QC results for the D-test were within the expected result range 100% (119/119) of the time.

**Inoculum Density Control:**
The DensiCHEK Plus was used to standardize the inoculum to a 0.5 McFarland standard. The instrument was standardized daily with all results recorded at each site. Calibration values were within the expected range.

**Purity Check:**
A purity check of all organisms was performed on the dilution tube used to prepare the VITEK 2 card inoculum. Only those cultures that were pure were evaluated in the study.

**Device Failure:**
During the performance of the comparative study, there were zero (0) device failures with the VITEK 2 System instruments.

**Growth Failure Rate:**
A total of 593 clinical and challenge isolates were tested by VITEK 2 AST-ST Inducible Clindamycin Resistance. No growth failures were recorded, and all 593 isolates had VITEK 2 AST-ST Inducible Clindamycin Resistance results available.

6. Assay Cut-Off:

Not applicable.

## B Comparison Studies:

1. Method Comparison with Predicate Device:

Testing of the VITEK 2 AST-ST Inducible Clindamycin Resistance was performed at three external sites and one internal site. Results were compared to results obtained with the D-test disk diffusion standard method. A 15 µg erythromycin disk was positioned 15 mm (edge to edge) from a 2 µg clindamycin disk. Results of the VITEK 2 AST-ST Inducible Clindamycin Resistance are reported as Positive (inducible resistance to clindamycin) or Negative (no inducible resistance to clindamycin). The testing conditions for the standard method consisted of the following:

- Medium: MHA with 5% sheep blood
- Inoculum: Direct colony suspension
- Incubation: 35ºC; 20-24 hours

The VITEK 2 cards were inoculated with test organisms using the auto-dilution method (VITEK 2) and the manual dilution method (VITEK 2, VITEK 2 Compact, VITEK COMPACT PRO). All test inocula used for the VITEK 2 AST cards and the disk diffusion standard method were standardized using the DensiCHEK instruments.

A total of 543 *Streptococcus* clinical isolates were evaluated using auto-dilution and VITEK 2. Of these isolates, 50.6% were contemporary isolates (tested within six months of isolation) and 49.4% were stock isolates (no specific time from isolation). The clinical isolates included: 300 *Streptococcus pneumoniae* and 243 *Streptococcus* spp. β-hemolytic group (98 *Streptococcus agalactiae*, 68 *Streptococcus pyogenes*, 46 *Streptococcus dysgalactiae equisimilis*, 28 *Streptococcus canis*, and 3 *Streptococcus equi* subsp. *zooepidemicus*).

A total of 50 *Streptococcus* challenge isolates were evaluated at one external site (VITEK 2 and VITEK 2 Compact) or one internal site (VITEK COMPACT PRO). The challenge isolates included: 10 *Streptococcus pneumoniae*, 21 *Streptococcus agalactiae*, 18 *Streptococcus pyogenes,* and 1 *Streptococcus dysgalactiae equisimilis*)

The VITEK 2 AST-ST Inducible Clindamycin Resistance test consists of two wells, clindamycin at concentration of 0.5 µg/mL and clindamycin/erythromycin at concentration of 0.25/0.5 µg/mL. The VITEK 2 AST-ST Inducible Clindamycin Resistance interpretation is shown in **Table 3** below.

**Table 3. Interpretation of VITEK 2 AST-ST Inducible Clindamycin Resistance**

| Clindamycin 0.5 µg/mL | Clindamycin/Erythromycin 0.25/0.5 µg/mL | VITEK 2 ICR Interpretation |
|---|---|---|
| No Growth | No Growth | Negative |
| No Growth | Growth | Positive |
| Growth | No Growth | Negative |
| Growth | Growth | Negative |

ICR, Inducible Clindamycin Resistance

**Clinical and Challenge Data – VITEK 2 Auto-Dilution**

The results obtained from the 593 total isolates (543 clinical isolates and 50 challenge isolates) using the auto-dilution method with the VITEK 2 are summarized in **Table 4**. Since this is a qualitative test, only Category Agreement (CA) was assessed.

**Table 4. Performance of VITEK 2 AST-ST ICR with Clinical and Challenge Isolates: VITEK 2 Auto-Dilution**

| | Total | #CA | %CA | Neg | Pos | maj | vmj |
|---|---|---|---|---|---|---|---|
| ***Streptococcus pneumoniae*** | | | | | | | |
| **Clinical** | 300 | 296 | 98.7 | 300 | 0 | 4 | 0 |
| **Challenge** | 10 | 10 | 100 | 10 | 0 | 0 | 0 |
| **Combined** | 310 | 306 | 98.7 | 310 | 0 | 4 | 0 |
| ***Streptococcus* spp. β-hemolytic group** | | | | | | | |
| **Clinical** | 243 | 240 | 98.8 | 222 | 21 | 3 | 0 |
| **Challenge** | 40 | 40 | 100 | 19 | 21 | 0 | 0 |
| **Combined** | 283 | 280 | 98.9 | 241 | 42 | 3 | 0 |

**ICR** – Inducible Clindamycin Resistance
**Pos** – ICR Positive
**Neg** – ICR Negative
**CA** – Category Agreement
**maj** – Major Discrepancies
**vmj** – Very Major Discrepancies

Category agreement occurs when the interpretation of the result of the standard method agrees exactly with the interpretation of the VITEK 2 AST card.

For *Streptococcus pneumoniae* evaluated using the auto-dilution method with the VITEK 2, the overall CA was acceptable at 98.7% (**Table 4**). There were four major errors (1.3%) and no very major errors. Only ICR negative *Streptococcus pneumoniae* isolates were evaluated. Therefore, the following limitation was included in the device labeling.

*The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing: Inducible Clindamycin Resistance (icr02n): Streptococcus pneumoniae*

For *Streptococcus* spp. β-hemolytic group evaluated using the auto-dilution method with the VITEK 2, the overall CA was acceptable at 98.9% (**Table 4**). There were three major errors (1.2%) and no very major errors. When evaluating by individual species, *Streptococcus dysgalactiae equisimilis* had a major error rate of 4.8% (2/42), which is not acceptable. Due to the acceptable performance of the device with *S. dysgalactiae equisimilis* ICR-negative isolates (100%) and the fact that this is a qualitative test, the overall performance was considered acceptable with the following limitation included in the device labeling to address the major error rate:

*Perform an alternative method of testing prior to reporting of results when a Positive (+) result is obtained with the following antibiotic/organism combination(s): Inducible Clindamycin Resistance (icr02n): Streptococcus dysgalactiae equisimilis*

**Challenge Data –VITEK 2, VITEK 2 Compact, and VITEK COMPACT PRO Manual Dilution**

The 50 challenge isolates were evaluated at one external site using the manual dilution with the VITEK 2 and VITEK 2 Compact Systems, and one internal site using the manual dilution method with the VITEK COMPACT PRO (summarized in **Table 5**)

**Table 5. Performance of VITEK 2 AST-ST ICR with Challenge Isolates: VITEK 2, VITEK 2 Compact and VITEK COMPACT PRO Manual Dilution**

| | Total | #CA | %CA | Neg | Pos | maj | vmj |
|---|---|---|---|---|---|---|---|
| ***Streptococcus pneumoniae*** | | | | | | | |
| **VITEK 2** | 10 | 10 | 100 | 10 | 0 | 0 | 0 |
| **VITEK 2 Compact** | 10 | 10 | 100 | 10 | 0 | 0 | 0 |
| **VITEK2 COMPACT PRO** | 10 | 10 | 100 | 10 | 0 | 0 | 0 |
| ***Streptococcus* spp. β-hemolytic group** | | | | | | | |
| **VITEK 2** | 40 | 40 | 100 | 19 | 21 | 0 | 0 |
| **VITEK 2 Compact** | 40 | 40 | 100 | 19 | 21 | 0 | 0 |
| **VITEK2 COMPACT PRO** | 40 | 40 | 100 | 19 | 21 | 0 | 0 |

**ICR** – Inducible Clindamycin Resistance
**Pos** – ICR Positive
**Neg** – ICR Negative
**CA** – Category Agreement
**maj** – Major Discrepancies
**vmj** – Very Major Discrepancies

Category agreement occurs when the interpretation of the result of the standard method agrees exactly with the interpretation of the VITEK 2 AST card.

For *Streptococcus pneumoniae* evaluated using the manual dilution method with the VITEK 2, VITEK 2 Compact, and VITEK COPACT PRO, the overall CA was acceptable at 100% (**Table 5**) and there were no major errors and no very major errors.

For *Streptococcus* spp. β-hemolytic group evaluated using the manual dilution method with the VITEK 2, VITEK 2 Compact, and VITEK COMPACT PRO, the overall CA was acceptable at 100% (**Table 5**) and there were no major errors and no very major errors.

**Testing/Reporting MICs for Species Not Listed in the Indications for Use**

For this review, the interpretive criteria are applied to the organisms/organism groups according to the FDA STIC website. As required under 511A(b)(2)(C)(ii)(I) of the Federal Food, Drug and Cosmetic Act, the following statement was added to the package insert to address testing and reporting of species not listed in the Indications for Use:

*Per the FDA-Recognized Susceptibility Test Interpretive Criteria website, the safety and efficacy of antimicrobial drugs, for which antimicrobial susceptibility is tested by this AST device, may or may not have been established in adequate and well-controlled clinical trials for treating clinical infections due to microorganisms outside of those found in the indications and usage in the drug label. The clinical significance of susceptibility information in those instances is unknown. The*

*approved labeling for specific antimicrobial drugs provides the uses for which the antimicrobial drug is approved.*

2. Matrix Comparison:

Not applicable.

**C Clinical Studies:**

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Clinical Cut-Off:

Not applicable.

4. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

**D Expected Values/Reference Range:**

Positive: Inducible resistance to clindamycin
Negative: No inducible resistance to clindamycin

**VIII Proposed Labeling:**

The labeling supports the finding of substantial equivalence for this device.

**IX Conclusion:**

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