

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

k070172

B. Purpose for Submission:

To add the option for automated swab specimen preparation and control preparation using the software accessory “Roche Scripts for AMPLICOR™ CT/NG Test for *Neisseria gonorrhoeae*” to direct the Tecan Genesis RSP 150 Workstation.

C. Measurand:

Neisseria gonorrhoeae DNA

D. Type of Test:

Qualitative determination using Polymerase Chain Reaction (PCR) DNA amplification and colorimetric detection

E. Applicant:

Roche Diagnostics Corporation

F. Proprietary and Established Names:

AMPLICOR™ CT/NG Test for *Neisseria gonorrhoeae*; Roche Scripts for AMPLICOR CT/NG Test (Roche Scripts Accessory)

G. Regulatory Information:

1. Regulation section:
866.3390 *Neisseria* species, Direct Serological Test Reagents
2. Classification:
Class II
3. Product code:
LSL - DNA reagents, *Neisseria*
4. Panel:
83 Microbiology

H. Intended Use:

1. Intended use:
The AMPLICOR CT/NG test for *Neisseria gonorrhoeae* is a qualitative in vitro test for the detection of *N. gonorrhoeae* DNA in urine from symptomatic or asymptomatic males,

in endocervical swab specimens from symptomatic or asymptomatic females, and in urethral swab specimens from symptomatic males as evidence of infection with *N. gonorrhoeae*. *N. gonorrhoeae* DNA is detected by Polymerase Chain Reaction (PCR) amplification of target DNA and by hybridization capture of amplified target.

Sample and control preparation can either be accomplished manually or automated using the optional Roche Scripts for AMPLICOR CT/NG Test Accessory to direct the Tecan Genesis RSP 150 Workstation. Urine specimens are not indicated for use with the automated sample preparation option.

The Roche Scripts for AMPLICOR CT/NG Test are intended to provide software scripts to direct the automated Tecan Genesis RSP 150 workstation to process swab samples or control material for analysis using either of the following four 510(k)-cleared assay test systems:

- AMPLICOR ® CT/NG test for *Chlamydia trachomatis*
- AMPLICOR ® CT/NG test for *Neisseria gonorrhoeae*

2. Indication(s) for use:

Same as intended use

3. Special conditions for use statement(s):

Urine specimens are not indicated for use with the automated sample preparation option. Prescription Use only.

4. Special instrument requirements:

Not applicable

I. Device Description:

The AMPLICOR CT/NG Test for *Neisseria gonorrhoeae* with optional Roche Scripts accessory is a qualitative in vitro diagnostic test for the detection of *Neisseria gonorrhoeae* DNA performing automated swab specimen preparation with the Tecan Genesis RSP 150 workstation.

The RSP Genesis 150 Workstation with Gemini software v4.2 is a microprocessor controlled sample diluter and dispenser. The Roche Scripts for AMPLICOR™ CT/NG Test accessory consists of a compact disc (CD) containing scripts to direct the automated Tecan Genesis RSP 150 workstation with Gemini software v4.2 to process swab samples or control material for analysis.

J. Substantial Equivalence Information:

1. Predicate device name(s):

AMPLICOR™ CT/NG test for *Neisseria gonorrhoeae*

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

k974503

3. Comparison with predicate:

Similarities		
Item	Device AMPLICOR™ CT/NG for <i>N. gonorrhoeae</i> with optional Roche Scripts accessory	Predicate AMPLICOR™ CT/NG for <i>N. gonorrhoeae</i>
Intended Use	<p>The AMPLICOR CT/NG test for <i>Neisseria gonorrhoeae</i> is a qualitative in vitro test for the detection of <i>N. gonorrhoeae</i> DNA in endocervical swab specimens from symptomatic or asymptomatic females, and in urethral swab specimens from symptomatic males as evidence of infection with <i>N. gonorrhoeae</i>. <i>N. gonorrhoeae</i> DNA is detected by Polymerase Chain Reaction (PCR) amplification of target DNA and by hybridization capture of amplified target.</p> <p>Sample and control preparation can either be accomplished manually or automated using the optional Roche Scripts for AMPLICOR CT/NG Test accessory to direct the Tecan Genesis RSP 150 workstation.</p> <p>Urine specimens are not indicated for use with the automated sample preparation option.</p> <p>The Roche Scripts for AMPLICOR CT/NG Test are intended to provide software scripts to direct the automated Tecan Genesis RSP 150 workstation to process swab samples or control material for analysis using either of the following four 510(k)-cleared assay test systems:</p> <ul style="list-style-type: none"> • AMPLICOR ® CT/NG test for <i>Chlamydia trachomatis</i> • AMPLICOR ® CT/NG test for <i>Neisseria gonorrhoeae</i> 	<p>The AMPLICOR CT/NG test for <i>Neisseria gonorrhoeae</i> is a qualitative in vitro test for the detection of <i>N. gonorrhoeae</i> DNA in urine from symptomatic or asymptomatic males, in endocervical swab specimens from symptomatic or asymptomatic females, and in urethral swab specimens from symptomatic males as evidence of infection with <i>N. gonorrhoeae</i>. <i>N. gonorrhoeae</i> DNA is detected by Polymerase Chain Reaction (PCR) amplification of target DNA and by hybridization capture of amplified target.</p>

Similarities		
Item	Device AMPLICOR™ CT/NG for <i>N. gonorrhoeae</i> with optional Roche Scripts accessory	Predicate AMPLICOR™ CT/NG for <i>N. gonorrhoeae</i>
Test Principle	DNA detection via PCR amplification of target DNA followed by hybridization capture, and colorimetric absorbance determination performed on the AMPLICOR™ Analyzer.	Same
Controls provided	<u>Positive control</u> : plasmid DNA from <i>N. gonorrhoeae</i> <u>Negative control</u> : DNA from <i>C. trachomatis</i> <u>Optional internal control</u> : plasmid DNA with <i>N. gonorrhoeae</i> primer binding regions and a unique probe binding region	Same

Differences		
Item	Device	Predicate
Specimen type	<ul style="list-style-type: none"> • Endocervical swab specimens from symptomatic or asymptomatic females • Urethral swab specimens from symptomatic males 	<ul style="list-style-type: none"> • Urine from symptomatic or asymptomatic males • Endocervical swab specimens from symptomatic or asymptomatic females • Urethral swab specimens from symptomatic males
Analytical sensitivity - Limit of Detection, Expressed as Colony Forming Units/mL (CFU/mL)	100 CFU/mL for <i>N. gonorrhoeae</i> with swab specimens	400 CFU/mL for <i>N. gonorrhoeae</i> with swab specimens (100 CFU/mL for <i>N. gonorrhoeae</i> with urine specimens)
Specimen and Control preparation	Manual or automated using the Roche Scripts to direct the Tecan Genesis RSP 150 workstation	Manual

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

CLSI EP5-A2 “Evaluation of Precision Performance of Quantitative Measurement Methods”, CLSI EP12-A “User Protocol for Evaluation of Qualitative Test Performance”.

L. Test Principle:

DNA detection via PCR amplification of target DNA followed by hybridization capture of amplified target using the AMPLICOR™ Analyzer. The PCR-based test system reagents and testing procedures are unchanged.

M. Performance Characteristics (if/when applicable):

The purpose of this submission is to demonstrate equivalency between the automated specimen preparation using Roche Scripts to direct the Tecan Genesis TSP 150, and the manual specimen preparation method.

1. Analytical performance:

a. *Precision/Reproducibility:*

The precision of the AMPLICOR CT/NG Test for *Neisseria gonorrhoeae* with automated specimen preparation was determined a multi-operator study. Three independent operators using three different Tecan Genesis RSP 150 Instruments tested two panels of culture transport media specimens containing samples described in the table below. The two panels were prepared on separate days but were identical in composition. The first panel was tested by all three sites. The first two sites tested the panel in triplicate, once a day. The third site tested the panel in triplicate on nine separate days over a period of three weeks. The second panel was tested by only one site in triplicate, once a day, over a period of five days. Each run consisted of automated specimen preparation using the Roche Scripts to direct the Tecan Genesis RSP 150 Instrument, followed by amplification and detection according to the standard test protocol.

Description of Panels used for Precision Testing:

Panel Sample	Description
PS1	Spiked M4 media at ~500 IFU/mL CT*
PS2	Spiked M4 media at ~300 IFU/mL CT
PS3	Spiked M4 media at ~100 IFU/mL CT
PS4	Spiked M4 media at ~100 IFU/mL CT and ~5000 cfu/mL NG**
PS5	Spiked M4 media at ~300 IFU/mL CT and ~3000 cfu/mL NG
PS6	Spiked M4 media at ~500 IFU/ml CT and ~1000 cfu/mL NG
PS7	Spiked M4 media at ~1000 cfu/mL NG
PS8	Spiked M4 media at ~3000 cfu/mL NG
PS9	Spiked M4 media at ~5000 cfu/mL NG
PS10	Spiked M4 media at ~500 IFU/mL CT and ~5000 cfu/mL NG
PS11	M4 media blank

*CT = *Chlamydia trachomatis*

**NG = *Neisseria gonorrhoeae*

Summary of Result for Precision: AMPLICOR™ CT/NG for *N. gonorrhoeae*:

Panel Member	Number of Replicates	Number of Correct Results*	Percentage of Correct Results*	Number of Initially Equivocal Results+	Percentage of Initially Correct Results
PS1	63	63	100.0%	0	100.0%
PS2	63	63	100.0%	0	100.0%
PS3	63	63	100.0%	2	96.8%
PS4	63	63	100.0%	4	93.7%
PS5	63	61	96.8%	10 ^x	84.1%
PS6	63	63	100.0%	1	98.4%
PS7	63	62	98.4%	5 ^{xx}	92.1%
PS8	63	63	100.0%	3	95.2%
PS9	63	63	100.0%	0	100.0%
PS10	63	63	100.0%	2	96.8%
PS11	63	62	98.4%	1 ^{xxx}	98.4%
overall	693	689	99.4%	18	96.0%

*Samples with absorbance values of ≥ 2.0 were considered positive, and samples with absorbance value < 2.0 negative in this set of calculations, based on the package insert instructions for repeat testing

+Initially equivocal samples had an absorbance of ≥ 0.2 and < 3.5

^xA₄₅₀ for 8 out of 10 equivocal results was within 2.000-3.499 range (and A₄₅₀ for two was 0.200-1.999)

^{xx}A₄₅₀ for 4 out of 5 equivocal results was within 2.000-3.499 range), and A₄₅₀ for 1 was 0.200-1.999

^{xxx}A₄₅₀ for the equivocal result was within 0.200-1.999 range

The overall precision of the automated method using a cutoff of 2.0 is 99.4%, compared to the precision of the manual method of 99.6%. When calculations are

based on using initially equivocal results, overall precision of the automated method is 96.0%, and manual 98.4%.

b. *Linearity/reportable range:*
Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
The recommended Positive, Negative and Internal Control material were tested a sufficient number of times with acceptable results on all testing days.

d. *Detection limit:*

The analytical sensitivity of the AMPLICOR CT/NG Test for *Neisseria gonorrhoeae* with automated specimen preparation was determined by testing *N. gonorrhoeae* ATCC strain 19242. Stock cultures of *N. gonorrhoeae* were diluted in M4RT media to prepare specimens that contained 500, 400, 250, 200, 100, and 50 cfu/mL. Following automated specimen preparation using the Roche Scripts to direct the Tecan Genesis RSP 150 Instrument, the specimens were amplified and detected according to the standard test protocol.

A total of 24 replicates per dilution for each sample processing/testing combination were tested. Equivocal results were not repeated, and samples returning inhibitory results were excluded from data analysis. Absorbance values ≥ 2.0 were considered positive, and < 2.0 negative.

The analytical sensitivity (limit of detection) was defined as the lowest dilution at which $\geq 95\%$ of all replicates yielded positive results. The analytical sensitivity of the AMPLICOR CT/NG Test for *Neisseria gonorrhoeae* with automated specimen preparation is 100 cfu/mL. **This result differs from the current labeled LoD of 400 CFU/mL.** The results of study are presented in the table below.

Summary of LoD for AMPLICOR™ CT/NG Test for *N. gonorrhoeae* with automated and manual specimen preparation:

Sample cfu/mL	Dilution	N	Automated		N	Manual	
			Positive	%		Positive	%
NG-1 0.62	50	24	22	91.7	24	20	83.3
NG-2 1.25	100	24	23	95.8	24	24	100.0
NG-3 2.5	200	24	23	95.8	24	24	100.0
NG-4 3.12	250	24	24	100.0	24	24	100.0
NG-5 5	400	24	24	100.0	24	23	95.8
NG-6	500	24	24	100.0	24	24	100.0

6.25							
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e. *Analytical specificity:*

The analytical specificity was tested using the automated sample preparation directed by the Roche Scripts compared to the manual method by examining spiked samples with varying concentrations of the test analytes. The same method and concentrations used in the Precision panel testing were utilized for analytical specificity. Data from the different sites were pooled and the percentage of false positives and negatives were calculated. The following table shows the agreement of the specificity results between the automated and the manual methods.

Specificity results for AMPLICOR CT/NG test for *N. gonorrhoeae*:

		AMPLICOR CT/NG test for <i>N. gonorrhoeae</i>					
		Automated*		N	Manual**		
Positive Samples	N	False negatives	%		False negatives	%	
PS4	63	0	0.0	63	0	1.6	
PS5	63	0	0.0	63	0	0.0	
PS6	63	0	0.0	63	0	0.0	
PS7	63	0	0.0	63	0	0.0	
PS8	63	0	0.0	63	0	0.0	
PS9	63	0	0.0	63	0	0.0	
PS10	63	0	0.0	63	0	0.0	
Overall	441	0	0.0	441	0	0.0	
Negative Samples		False positives			False positives		
PS1	63	0	0.0	63	0	0.0	
PS2	63	0	0.0	63	1	1.6	
PS3	63	0	0.0	63	0	0.0	
PS11	63	1	1.6	63	0	0.0	
Overall	252	1	0.4	252	0	0.4	

*The automated sample preparation had 27 equivocal results

**The manual sample preparation had 10 equivocal results

The false negative rate and false positive rate for automated sample preparation are within 95% of false negative and false positive rate for manual sample preparation. The analytical specificity automated results are equivalent to the manual method results.

f. *Assay cut-off:*

Not applicable

g. *Cross-Contamination Testing*

This study evaluated the potential for cross contamination / carryover of the AMPLICOR™ CT/NG for *N. gonorrhoeae* assay with automated sample

preparation directed by the Roche Scripts; in comparison to manual sample preparation. This study was designed to observe the effects of potential aerosolization / splash over the whole plate. Positive specimens or M4 media blanks were prepared as samples.

Positive samples were prepared from stock cultures of *Neisseria gonorrhoeae* (ATCC 19242) at 1.0×10^8 IFU/mL diluted in M4 media and *C. trachomatis* (ATCC strain Vr 885, Serovar D) at 1.44×10^7 IFU/mL. High concentration of $\sim 10,000$ IFU/mL of *N. gonorrhoeae* alone and $\sim 10,000$ IFU/mL of both *C. trachomatis* and *N. gonorrhoeae* combined were utilized. Map layouts on the 96-well microtiter plates were constructed to provide adequate opportunity to observe cross-contamination over multiple plate positions, including a ‘worst case’ scenario of blanks surrounded by positives; and to provide a sufficient number of blanks to calculate a false positive rate. In addition, a checkerboard pattern was used to further challenge the performance of the system. Testing was performed over five days. The overall false positive rate was 0.3% (1/370) with automated specimen preparation and 1.6% (6/370) with manual preparation. The differences in the false positivity rates are not statistically significant at the 95% confidence level.

2. Comparison studies:

a. *Method comparison with predicate device:*

A prospective study was performed in order to establish that the results obtained using the automated specimen preparation option are equivalent to results obtained using the manual specimen preparation option when tested in parallel and compared to culture.

Two swab specimens were collected from 296 patients. One swab was sent for *N. gonorrhoeae* culture and the other swab was placed in M4RT culture transport media and used for AMPLICOR testing. An aliquot of each M4RT sample was removed and processed manually, and each sample was also subjected to automated specimen preparation using the Roche Scripts to direct the Tecan Genesis RSP 150 Instrument. The specimens were amplified and detected using the AMPLICOR CT/NG Test for *Neisseria gonorrhoeae* according to the standard test protocol. An initial qualitative test result (positive, negative, equivocal, or inhibitory) was assigned for each sample according to the method manual. Samples were repeated in the case of failed (invalid) run controls. Samples yielding equivocal or inhibitory results were repeated according to package insert directions (i.e., repeated in duplicate) by sampling from the original sample tube, and the final result was used in the data analysis.

Eight samples were excluded from the data analyses : 1 because a culture result was not obtained, 2 because of missing specimen chain of command paperwork, 5 after giving repeat results of “inhibitory” with both manual and automated test methods; resulting in 288 valid data sets. All 5 repeatedly inhibitory specimens came from females and all five yielded negative culture results. The results from the 288 valid

data sets are summarized in tables below as an overall comparison to culture of all samples, and stratified by specimen type: female endocervical and male urethral swabs.

Overall three-way method comparison results for AMPLICOR CT/NG Test for *Neisseria gonorrhoeae* comparing automated and manual specimen preparation and culture:

Method Result		Total Specimens	Culture Result	
Test Method*	Comparative Method*		Positive	Negative
Positive	Positive	129	109	20
Positive	Negative	1	0	1
Negative	Positive	2	0	2
Negative	Negative	156	2	154
Total		288	111	177

*the Test Method was the automated and the Comparative Method was the manual specimen preparation

Three-way method comparison results for AMPLICOR CT/NG Test for *Neisseria gonorrhoeae* comparing automated and manual specimen preparation and culture for **endocervical swab specimens** (females):

Method Result		Total Specimens	Culture Result	
Test Method	Comparative Method		Positive	Negative
Positive	Positive	69	51	18
Positive	Negative	1	0	1
Negative	Positive	2	0	2
Negative	Negative	106	2	104
Total		178	53	125

Three-way method comparison results for AMPLICOR CT/NG Test for *Neisseria gonorrhoeae* comparing automated and manual specimen preparation and culture for **urethral swab specimens** (males):

Method Result		Total Specimens	Culture Result	
Test Method	Comparative Method		Positive	Negative
Positive	Positive	60	58	2
Positive	Negative	0	0	0
Negative	Positive	0	0	0
Negative	Negative	50	0	50
Total		110	58	52

A secondary analysis was also conducted. For each of the 293 data sets (288 from the main analysis plus 5 with inhibitory results), the concordance between results obtained using the automated and manual preparation methods was calculated. The 5

specimens that were inhibitory upon repeat testing by both methods were deemed concordant in these calculations. The percent positive and percent negative agreements with 95% confidence intervals were also calculated. These comparative analyses were also performed on sample sets stratified by gender. The results are given in following table:

Concordance analysis results for AMPLICOR CT/NG Test for *Neisseria gonorrhoeae* comparing automated and manual specimen preparation:

Test	Comparison	Fraction	Agreement	95% Confidence Interval
NG Automated	Overall	Concordance	290 / 293	99.0% (97.0% - 99.8%)
		%Pos Agreement	129 / 131	98.5% (94.6% - 99.8%)
		%Neg Agreement	156 / 157	99.4% (96.5% - 100.0%)
	Male	Concordance	110 / 110	100.0% (96.7% - 100.0%)
		%Pos Agreement	60 / 60	100.0% (94.0% - 100.0%)
		%Neg Agreement	50 / 50	100.0% (92.9% - 100.0%)
	Female	Concordance	180 / 183	98.4% (95.3% - 99.7%)
		%Pos Agreement	69 / 70	98.6% (92.3% - 100.0%)
		%Neg Agreement	106 / 108	98.1% (93.5% - 99.8%)

b. *Matrix comparison:*
Not applicable

3. Clinical studies:

a. *Clinical Sensitivity:*
Not applicable

b. *Clinical specificity:*
Not applicable

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

4. Clinical cut-off:

The cutoffs for the *N. gonorrhoeae* specimen results and the Internal Control (IC) specimen results were determined in the previous submission for AMPLICOR™ CT/NG for *N. gonorrhoeae* (k974503).

5. Expected values/Reference range:

Interpretation of the results (with Internal Control detection):

NG Result A ₄₅₀	IC Result A ₄₅₀	Interpretation
< 0.2	≥ 0.2	<i>N. gonorrhoeae</i> not detected.
< 0.2	< 0.2	Inhibitory specimen.
≥ 3.5	Any	<i>N. gonorrhoeae</i> DNA detected.
≥ 0.2, <3.5	Any	Equivocal. Process another aliquot of the original specimen and repeat the test in duplicate*

* The final test interpretation of these specimens should be determined using 2.0 A₄₅₀ as the cutoff. Specimens with at least 2 out of 3 results with A₄₅₀ ≥ 2.0 should be considered positive for *N. gonorrhoeae*. If 2 out of 3 results have an A₄₅₀ less than 2.0, the specimen is presumptive negative for *N. gonorrhoeae*.

N. Instrument Name:

Tecan Genesis RSP-RC 150 Workstation Instrument, with Roche Scripts accessory

O. System Descriptions:

1. Modes of Operation:

The Genesis RSP 150 Workstation is a multiple task liquid handling system that combines a system of microprocessor-controlled liquid handling and other components to one instrument. The User controls the system via a personal computer, equipped with the Genesis Instrument Software, Gemini Software v4.2, and the Roche Scripts. Genesis RSP is designed to handle liquid volumes ranging between 0.5 µL and 5 µL depending on the installed configuration.

The liquid system is the central component of Genesis pipetting function. It transmits the precise movement of the diluter pistons to the tips through the system liquid. The system liquid is delivered to the system in a container and is aspirated and distributed in the whole system via tubes, valves and connectors. The distribution of the system liquid is effected by the movement of the diluter pistons in several strokes. Disposable tips with filter shall be used where no carry over is tolerable.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types in submission K963268:

Yes or No

3. Specimen Identification:

The Positive Identification (PosID2) reads Barcodes on Carriers, Racks and Containers on both, the primary, e.g. sample tube, as well as the secondary side, e.g. microplates by means of a scanner. With its gripper, it pulls carriers towards the rear of the instrument for barcode identification on tubes and microplates, and then, pushes the carrier back into operating position. To use the PosID2, all carriers, racks and containers (sample tubes, microplates, reagent bottles, troughs) must be labeled with barcodes. Exact positioning of these labels is required for optimal function.

4. Specimen Sampling and Handling:

To minimize the potential for well-to-well carryover, the Roche Scripts direct the liquid handling arms of the Tecan RSP 150 to discard the pipet tip immediately after any pipetting step involving contact with a sample- or control containing well. Design features intended to minimize the potential for cross-contamination via aerosolization and splashing are listed below:

- Use of disposable pipet tips with aerosol barrier filters
- Low disposable tip eject option: tips are ejected into a narrow slit box to reduce aerosolization during the ejection step
- Use of a deep well plate for extraction steps

The Gemini 4.2 software and the Tecan Genesis RSP 150 have liquid class settings which control the accuracy of the aspiration and dispense functions of the liquid handling arm. These liquid classes have several sub-options which are configured to the liquid being handled. The sub-options include:

- LAG, STAG, TAG (air gap settings at specific places within the pipet tip)
- Rate / speed of aspiration and dispense settings
- Position of pipet tip in well to optimize liquid aspiration
- Mixing characteristics

5. Calibration:

Liquid class handling settings are determined for each liquid by performing volumetric test cases. The documentation for the test cases is provided in the submission.

6. Quality Control:

An on-line interactive Troubleshooting guide normally detects problems and offers immediate advice for corrective actions pertaining to operations, communication, positioning, and identification errors. Daily, weekly, and periodic preventative maintenance schedules are provided in the Tecan User Manual.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:

The sponsor acknowledges that the analytical studies cited in the risk assessment as controls for the Tecan functions are more properly identified as verification activities. Roche audited Tecan, and confirmed that Tecan validated the Gemini v4.2 software.

The Roche Scripts CD’s are standalone software designed to run on Off-the-Shelf (OTS) Tecan equipment. Roche Scripts are installed at the user site in read-only mode, and cannot be altered by the User.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

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