K042357

OCT 2 2 2004

510(k) Summary

Infectio Diagnostic Inc. IDI-MRSA™ assay
Special 510(k)

August 28, 2004

Submitted by: Infectio Diagnostic Inc.
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Sainte-Foy, Québec
Canada
G1V 2K8

Contact: Patricia Dionne, PhD.

Name of Device:

Trade Name:	IDI-MRSA™ Assay
Common Name:	Test kit for the detection of methicillin-resistant *Staphylococcus aureus*
Product Code:	NQX
Classification Name	System, Nucleic Acid Amplification Test, DNA, Methicillin Resistant *Staphylococcus aureus*, Direct Specimen
Predicate Device:	Infectio Diagnostic Inc. IDI-MRSA™ Assay

Device Description:

Intended Use:

IDI-MRSA™ assay is a qualitative *in vitro* diagnostic test for the direct detection of nasal colonization by methicillin-resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings. The test performed on the Smart Cycler® instrument with a nasal swab specimen from patients at risk for colonization, utilizes polymerase chain reaction (PCR) for the amplification of MRSA DNA and fluorogenic target-specific hybridization probes for the detection of the amplified DNA.

IDI-MRSA is not intended to diagnose MRSA infections nor to guide or monitor treatment for MRSA infections. Concomitant cultures are necessary only to recover organisms for epidemiological typing or for further susceptibility testing.

Test Description:

A nasal specimen is collected and transported to the laboratory using the Copan Venturi Transystem®. For testing, the swab is placed in sample preparation buffer. The specimen is concentrated and lysed. An aliquot of the lysate is added to PCR reagents which contain the MRSA-specific primers used to amplify the genetic target [a sequence near the insertion site of Staphylococcal Cassette Chromosome *mec* (SCC*mec*)], if present. The assay also includes an internal control (IC) used to detect PCR inhibitory specimens and to confirm the integrity of assay reagents in negative specimens. Amplified targets are detected with hybridization probes

labeled with quenched fluorophores (molecular beacons). The amplification, the detection of fluorescence and the interpretation of signals are done automatically by the Smart Cycler® Instrument. The whole procedure takes about 60 to 75 minutes, depending on the number of specimens processed. For the recovery of MRSA for epidemiological typing or for further antibiotic susceptibility testing, appropriate culture media can be inoculated during specimen preparation or up to 24 hours after its preparation.

Substantial Equivalence:

This Special 510(k) is submitted for the following modifications to the Infectio Diagnostic Inc. IDI-MRSA™ assay:

Modification	Impact of modification
Development of a 200-tests format (cleared device is a 50-tests format)	Change in the workflow of the preparation of PCR reagents for specimens and controls. Positive and Negative Controls prepared by user.
Substitution with chemically modified DNA polymerase complex	Modification of formulation of existing materials and of PCR protocol to optimize reaction conditions for substituted DNA polymerase.
Upgrade of software version	Change not pertinent to IDI assay

Risk analysis performed on the changes did not raise new issues of safety and effectiveness. The parameters listed below were evaluated in comparison studies of the modified assay versus the original formulation. The modified assay met product claims for all parameters

Parameter	Result
Validation of cut-off	Equivalent to original formulation
Verification of amplified products	Estimated number of nucleic acids equivalent to their theoretical sizes
Limit of detection	Equivalent to original formulation
Analytical sensitivity towards different MREJ polymorphic groups	Equivalent to original formulation
Validation of analytical specificity	Equivalent to original formulation
Potentially interfering substances	Equivalent to original formulation
Performance with clinical specimens	Sensitivity and specificity meet claims; Rate of unresolved specimens equivalent to original formulation; Results agreement with original formulation >96%.
Reproducibility	Meets claims

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 2 2004

Infectio Diagnostic (I.D.I.), Inc.
c/o Sienna Partners, LLC
Ms. Judi Smith
Principal
P.O. Box 103
Baldwin, MD 21013

Re: k042357
Trade/Device Name: IDI-MRSA™ Assay
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: Class II
Product Code: NQX
Dated: October 15, 2004
Received: October 16, 2004

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

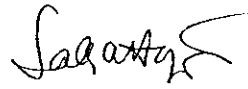
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

1 - INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K042357

Device Name: IDI-MRSA™

Indications For Use:

IDI-MRSA™ assay is a qualitative *in vitro* diagnostic test for the direct detection of nasal colonization by methicillin-resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings. The test performed on the Smart Cycler® instrument with a nasal swab specimen from patients at risk for colonization, utilizes polymerase chain reaction (PCR) for the amplification of MRSA DNA and fluorogenic target-specific hybridization probes for the detection of the amplified DNA.

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Prescription Use ✓ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Freddie T. Poole

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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