K101879

Cepheid.

JUL 28 2010

510(k) Summary

As required by 21 CFR Section 807.92(c).

Submitted by:	Cepheid 904 Caribbean Drive Sunnyvale, CA 90489 Phone number: (408) 400-8230 Fax number: (408) 541-6439
Contact:	Russel K. Enns, Ph.D.
Date of Preparation:	June 30, 2010
Device:	
Trade name:	Xpert® MRSA/SA Blood Culture Assay
Common name:	Methicillin-resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA) from positive blood culture bottles assay.
Type of Test:	Nucleic Acid Amplification Test, DNA, Methicillin-resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA), qualitative
Classification name:	Antimicrobial susceptibility test powder
Regulation number:	866.1640
Procode:	NQX
Classification Advisory Committee:	Microbiology
Panel:	83
Predicate Device:	Xpert® MRSA/SA Blood Culture Assay, 510(k) #K082140

Device Description:

The Cepheid Xpert® MRSA/SA Blood Culture Assay (Xpert MRSA/SA Blood Culture Assay) is a rapid, automated DNA test for simultaneously detecting MRSA and SA directly from positive blood culture specimens. The assay is performed on the Cepheid GeneXpert Dx System.

Device Intended Use:

The Cepheid Xpert™ MRSA/SA Blood Culture Assay performed on the GeneXpert® Dx System™ is a qualitative *in vitro* diagnostic test intended for the detection of *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) DNA directly from patient positive blood cultures. The assay utilizes automated real-time polymerase chain reaction (PCR) for the amplification of MRSA/SA specific DNA targets and fluorogenic target-specific hybridization probes for the real-time detection of the amplified DNA. The assay is performed directly on positive blood culture specimens using BD BACTEC™ Plus Aerobic/F blood culture bottles that are determined as Gram Positive Cocci in Clusters (GPCC) or as Gram Positive Cocci in singles (GPC) by Gram stain. The Xpert MRSA/SA Blood Culture Assay is indicated for use in conjunction with other laboratory tests, such as culture, and clinical data available to the clinician as an aid in the detection of MRSA/SA from patient positive blood cultures. Subculturing of positive blood cultures is necessary to recover organisms for susceptibility testing or for epidemiological typing. The Cepheid Xpert™ MRSA/SA Blood Culture Assay is not intended to monitor treatment for MRSA/SA infections.

When an MRSA negative/SA positive result is obtained, the result should be interpreted as "MRSA indeterminate/SA Positive, antimicrobial susceptibility testing pending". Further testing should be performed using an FDA-cleared, phenotypic antimicrobial susceptibility testing method on isolated colonies recovered from the blood culture bottle. MRSA positive/SA Positive results should be reported as such.

Substantial Equivalence:

The Xpert MRSA/SA Blood Culture Assay is substantially equivalent to the predicate device (Xpert MRSA/SA Blood Culture Assay; 510(k) #K082140, cleared on September 9, 2008). The two devices are identical in composition and technological characteristics; the only changes that have been made to the new device are to the package insert, as directed by the agency. The primary change includes the addition of a warning box statement to the Intended Use Statement, with related labeling changes to support the warning statement. The intended use of the device to detect *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) DNA directly from patient positive blood cultures has not changed.

Conclusion:

The Xpert MRSA/SA Blood Culture Assay with the labeling modifications is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

JUL 28 2010

Russel K. Enns, Ph.D.
Senior Vice President
Chief Regulatory Officer
Cepheid®
904 Caribbean Drive
Sunnyvale CA 94089-1189

Re: k101879

Trade/Device Name: Cepheid Xpert™ MRSA/SA Blood Culture Assay

Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: Class II
Product Code: NQX
Dated: July 2, 2010
Received: July 6, 2010

Dear Dr. Enns:

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K101879

Indications for Use Form

JUL 2 8 2010

510(k) Number (if known): K101879

Device Name: Xpert MRSA/SA Blood Culture Assay

Indications for Use:

The Cepheid Xpert™ MRSA/SA Blood Culture Assay performed on the GeneXpert® Dx System™ is a qualitative *in vitro* diagnostic test intended for the detection of *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) DNA directly from patient positive blood cultures. The assay utilizes automated real-time polymerase chain reaction (PCR) for the amplification of MRSA/SA specific DNA targets and fluorogenic target-specific hybridization probes for the real-time detection of the amplified DNA. The assay is performed directly on positive blood culture specimens using BD BACTEC™ Plus Aerobic/F blood culture bottles that are determined as Gram Positive Cocci in Clusters (GPCC) or as Gram Positive Cocci in singles (GPC) by Gram stain. The Xpert MRSA/SA Blood Culture Assay is indicated for use in conjunction with other laboratory tests, such as culture, and clinical data available to the clinician as an aid in the detection of MRSA/SA from patient positive blood cultures. Subculturing of positive blood cultures is necessary to recover organisms for susceptibility testing or for epidemiological typing. The Cepheid Xpert™ MRSA/SA Blood Culture Assay is not intended to monitor treatment for MRSA/SA infections.

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

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

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101879