K073537

510(k) Summary - revised JUN 27 2008

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter information

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Date summary prepared: June 18, 2008

Device Information

Proprietary Name: Neonatal Bilirubin (nBili) on Rapidlab® 1200 Blood Gas Systems

Common name: Neonate bilirubin on blood gas system

Classification name: Bilirubin in the neonate test system

Classification number: 21 CFR 862.1113, Class I reserved

Classification panel: Clinical Chemistry and Clinical Toxicology Devices

Predicate Devices

Element	Predicate I	Predicate II
Device Name	ABL800 FLEX	ABL735
Common name	Blood gas analyzer	Blood gas analyzer
510(k) Number	K043218	K991417
Manufacturer	Radiometer Medical ApS	Radiometer America

Device Description

Neonatal Bilirubin (nBili) is a new parameter enabled on models 1245 and 1265 of the Rapidlab® 1200 blood gas family of instruments. It is intended as an *in vitro* diagnostic test for the determination of total neonatal Bilirubin (nBili) concentration in the whole blood of newborn infants. Enabling the nBili measurement is accomplished through software design changes introduced in Rapidlab Software Version 2.1. No hardware /mechanical changes were needed.

Statement of Intended Use

The neonatal bilirubin test intended for use on the Rapidlab® 1245 and Rapidlab 1265 analyzers is an *in vitro* diagnostic test for the determination of total neonatal bilirubin (nBili) concentration in the whole blood of newborn infants. Measurement of nBili aids in assessing the risk of kernicterus.

Summary of Technological Characteristics

The measurement technology used for the Rapidlab 1200 systems family (including models 1245 and 1265) remain unchanged. Ability to measure neonate Bilirubin was enabled through software changes.

The Rapidlab 1200 System uses multiple wavelength spectrophotometry (CO-oximetry) to measure the transmission of light through a sample of neonate whole blood to determine concentrations of hemoglobin derivatives and bilirubin. The Rapidlab 1200 System aspirates the whole blood sample at the sample port and then transfers the sample to the CO-ox module. As the sample flows through an optical chamber, the CO-ox module optics head directs light through the sample and to a polychromator that measures the intensity of transmitted light at different wavelengths. Iterative least squares analysis is used to determine raw bilirubin values. Raw values are then corrected for hematocrit to produce nBili results.

Assessment of Performance

Studies were conducted to demonstrate the performance of the Rapidlab 1245 and 1265 with (nBili) parameter and assess substantial equivalence against the radiometer ABL735 and ABL800 FLEX (predicate devices).

The nBili internal evaluation study entailed testing concentrations of unconjugated bilirubin in oxygenated whole blood (neonatal type samples) across the reporting ranges. For a total of 2,241 samples, the coefficient of determination (r^2) values were well within the acceptance criteria (>.90) for all model, device, and mode combinations. Specimens were evaluated on both models (1245 and 1256) and against the predicate devices. Based on performance data analyzed it was concluded that the predetermined acceptance criteria was met.

In addition information on Software Development Life Cycle including software requirements specifications, risk management report, and overall verification and validation results were included to provide additional assurance of device performance.

Conclusion

In conclusion, the studies completed demonstrate that the Neonatal Bilirubin (nBili) on the Rapidlab 1245 and 1265 blood gas systems is similar to the predicate in both Technological Characteristics and Intended Use. The data presented in the submission is a summary of internal evaluation, external clinical evaluation, and software development information. This information provides assurance that the RapidLab 1200 analyzer (models 1245 and 1265) measuring neonate bilirubin has demonstrated substantial equivalence to the currently marketed radiometer predicate across the reporting range.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 27 2008

Siemens Healthcare Diagnostics Inc.
Point of Care (POC) Product Segment
c/o Noor Malki
POC, Regulatory Affairs
2 Edgewater Drive
Norwood, MA 02062

Re: k073537
Trade Name: Neonatal Bilirubin (nBili) on Rapiblab models 1245 and 1265
Regulation Number: 21 CFR 862.1113
Regulation Name: Bilirubin (total and unbound) in the neonate test system.
Regulatory Class: Class I reserved
Product Code: MQM
Dated: June 23, 2008
Received: June 24, 2008

Dear Noor Malki:

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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): 073537

Device Name: Neonatal Bilirubin (nBili)

Indications For Use:

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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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K073537