K013373

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III.
510(k) Summary

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510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
Contact Person: Jennifer Tribbett
Date Prepared: October 9, 2001

2) Device name

Proprietary name: Omni C Analyzer
Common name or Classification Name: pH, Blood Gas, Electrolyte, Hematocrit, Hemoglobin and Oxygen Saturation System

3) Predicate device

We claim substantial equivalence to the current legally marketed Omni Modular Analyzer (K990092).

4) Device Description

The Omni C analyzer represents a combined blood gas, electrolyte, total hemoglobin, hematocrit and oxygen saturation test system classified as a Class II device under various sections of 21 CFR 862 and 864 based on the individual test parameters measured.

5) Intended use

The Roche Diagnostics Omni C Analyzer is intended to be used for the measurement of pH, PO2, PCO2, sodium, potassium, ionized calcium, chloride, hematocrit, total hemoglobin and oxygen saturation in samples of whole blood, serum, plasma and aqueous solutions as appropriate.

Continued on next page

510(k) Summary, Continued

Comparison to Predicate Device

Similarities The following is a list of some of the claims and features unaffected by the proposed modification.

Feature/Claim	Detail
Intended use	In-vitro diagnostic device intended to measure blood gases, electrolytes, total hemoglobin and hematocrit.
Fundamental Technology	For electrolytes, PO2, PCO2, pH and hematocrit the technology is the same as the Omni Modular, thickfilm enzymatic and electrochemical. For the tHb/SO2 module, the technology is the same as the Opti R, optical reflectance.
Sample Type	Utilizes the same sample type (whole blood, serum, plasma, aqueous buffers, QC materials) for each parameters as previously cleared on the Omni Modular for the electrolytes, hematocrit, PO2, PCO2 and pH and as the Opti R for tHb/SO2.
Calibration	The liquid calibration system has the same calibration principle and utilizes the same calibration reagent formulations as the Omni Modular.
Device components	Omni C utilizes the same valves and peristaltic pump as those contained within the Omni Modular.
User Interface	Omni C uses the same GUI (touch screen) as the Omni Modular, except the Omni C footprint is slightly smaller.

Differences The following is a list of the claims and features affected by the proposed modification.

Feature/Claim	Detail
Parameter	Incorporates a tHb/SO2 module which is not offered on the Omni Modular but is a modification of the currently available Opti R tHb/SO2 module.
Quality Control	Utilizes a different QC material due to the tHb/SO2 module. However, this Quality Control formulation is based on the previously cleared OPTI-Check material.
Software	Incorporates software that functions with the tHb/SO2 module.
Hardware features	Utilizes a new outer housing and a modified user interface to enhance the intuitive features of the system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Jennifer Tribbett
Regulatory Affairs Specialist
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

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Re: k013373
Trade/Device Name: Omi C Analyzer
Regulation Number: 21 CFR 862.1600; 21 CFR 862.1145; 21 CFR 862.1665; 21 CFR 862.1170; 21 CFR 862.1120; 21 CFR 864.5620; 21 CFR 864.5600; 21 CFR 864.7500
Regulation Name: Potassium test system; Calcium test system; Sodium test system; Chloride test system; Blood gases ($P_{co}2$, P_o2) and blood pH test system; Automated hemoglobin system; Automated hematocrit instrument; Whole bood hemoglobin assays
Regulatory Class: Class II; Class II; Class II; Class II; Class II; Class II; Class II; Class II
Product Code: CEM; JFP; JGS; CGZ; CHL; GKR; GKF; GLY
Dated: October 10, 2001
Received: October 11, 2001

Dear Ms. Tribbett:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013373

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Indications for Use Statement

510(k) Number (if known): K013373
Device Name: Omni C Analyzer

Indications for Use:

The Roche Diagnostics Omni C Analyzer is intended to be used for the measurement of pH, PO2, PCO2, sodium, potassium, ionized calcium, chloride, hematocrit, total hemoglobin and oxygen saturation in samples of whole blood, serum, plasma and aqueous solutions as appropriate.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013373

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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