SENDX
MEDICAL, INC.
A RADIOMETER COMPANY

RADIOMETER COPENHAGEN

K080370

Section III - 510(k) Summary of Safety and Effectiveness

JUL 31 2008

1. SUBMITTER INFORMATION

A.	Establishment Registration:	2027541
B.	Manufacturing Site:	SenDx Medical, Inc.
C.	Company Address:	1945 Palomar Oaks Way Carlsbad, CA 92011
D.	Date Prepared:	February 5, 2008

2. CONTACT PERSON

A.	Mark A. Dzendzel:	Manager, Regulatory Affairs and Quality Systems
B.	Phone:	760-603-3412
C.	Fax:	760-930-6310
D.	Email:	mdzendzel@sendx.com

3. DEVICE IDENTIFICATION

A.	Trade/Proprietary Name:	ABL80 FLEX CO-OX
B.	Classification:	Class II (21CFR § 862.1120)
C	Product Code:	75CHL
D.	Subsequent Codes:	75JGS 75CEM, 75JFP, 75CGZ, 75CGA, 75GKR, 75DQA, 75GHS

4. DEVICE DESCRIPTION

The *ABL80 FLEX CO-OX* system consists of a modular analyzer incorporating a user interface module with a large color touch screen interfacing to analyzer electronic and fluidic modules. The user interface module contains the analyzer CPU and all of the required electronic interfaces for external communication and data storage.

Sensors that measure pH, pCO_2, pO_2, cCa^{2+}, cCl^-, cK^+ cNa^+ and *c*Glu are contained in a cassette that also contains the sample inlet. This cassette attaches to the front of the analyzer.

The oximetry module measures *c*tHb, sO_2, FO_2Hb, *F*COHb, *F*MetHb and *F*HHb. This module consists of a spectrometer, an ultrasonic hemolyzer and thermostatic components integrated into the analyzer.

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The system also includes a reagent cartridge for the calibration and automatic quality control of the sensor and oximetry system. The calibration and quality control reagents are packaged in sealed foil pouches.

The analyzer and consumables incorporate "smart chip" technology for unique identification and lot specific calibration and quality control data.

5. INTENDED USE / INDICATIONS FOR USE

The *ABL80 FLEX CO-OX* is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose and oximetry in whole blood. The *ABL80 FLEX CO-OX* system is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting.

6. SUBSTANTIAL EQUIVALENCE

The *ABL80 FLEX CO-OX* is substantially equivalent in features and characteristics to the predicate *ABL80 FLEX* and the *ABL700*.

510(k) Number	Device	Manufacturer
K051804	*ABL80 FLEX*	SenDx Medical, Inc.
K980130	*ABL700* Series	Radiometer Medical ApS

With each of the listed devices and the *ABL80 FLEX CO-OX,* the principles of operation are similar:

- Amperometry — pO_2, Glucose
- Potentiometry — pH, cNa^+, cK^+, cCa^{2+}, cCl^-, pCO_2
- Spectrophotometry — $ctHb$, sO_2, FO_2Hb, $FCOHb$, $FMetHb$ and $FHHb$

7. PERFORMANCE DATA

The *ABL700* will be used for the following data:

A. Method Comparison:

B. Precision

C. Linearity/Assay Reportable Range

D. Calibration/Quality Control

E. Analytical specificity - Interference

F. User Testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SenDx Medical, Inc.
c/o Mr. Mark A. Dzendzel
Manager Regulatory Affairs & Quality Systems
1945 Palomar Oaks Way
Carlsbad, CA 92011

JUL 31 2008

Re: k080370
Trade Name: ABL80 Flex Co-Ox
Regulation Number: 21 CFR 864.5620
Regulation Name: Automated hemoglobin system
Regulatory Class: Class II
Product Codes: GKR, GHS, GLY, JJY, CHL, JGS, CEM, JFP, CGZ, CGA
Dated: June 16, 2008
Received: June 20, 2008

Dear Mr. Dzendzel:

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): k080370

Device Name: ABL80 FLEX CO-OX

Indications for Use:

The ABL80 FLEX CO-OX is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose and oximetry in whole blood. The ABL80 FLEX CO-OX system is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting.

These tests are only performed under a physician's order:

pH, pO_2,and pCO_2, : pH, pCO_2 and pO_2 measurements are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Potassium (cK^+): potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

Sodium (cNa^+): sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic secretion, or other diseases involving electrolyte imbalance.

Calcium (cCa^{2+}): calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

Chloride (cCl^-): chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such a cystic fibrosis and diabetic acidosis.

Glucose (cGlu): glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

The following six parameters will be introduced with the ABL80 FLEX CO-OX:

Total Hemoglobin (ctHb): total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

sO_2: oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus reduced hemoglobin.

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Office of In Vitro Diagnostic Device Evaluation and Safety

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FO_2Hb: oxyhemoglobin as a fraction of total hemoglobin.

FCOHb: carboxyhemoglobin measurements are used to determine the carboxyhemoglobin content of human blood as an aid in the diagnosis of carbon monoxide poisoning.

FMetHb: methemoglobin as a fraction of total hemoglobin.

FHHb: reduced hemoglobin as a fraction of total hemoglobin.

Prescription Use ___x___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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