DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 6, 2015

SENDX MEDICAL INC.
LASSE MOLLER
REGULATORY AFFAIRS SPECIALIST
AAKANDEVEJ 21
BROENSHOEJ 2700 DENMARK

Re: K151856
Trade/Device Name: ABL80 FLEX CO-OX with AQURE Connectivity
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (PCO2, PO2) and blood pH test system
Regulatory Class: II
Product Code: CHL, JGS, CEM, JFP, CGZ, CGA, GKR, DQA, GHS, JPI
Dated: July 3, 2015
Received: July 8, 2015

Dear Lasse Moller:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k151856

Device Name
ABL80 FLEX CO-OX with AQURE connectivity

Indications for Use *(Describe)*
Intended Use:
The ABL80 FLEX CO-OX analyzer is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, and oximetry in whole blood. The ABL80 FLEX CO-OX analyzer 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.

Indications for use:
These tests are only performed under a physicians order:
pH, pO2,and pCO2, : pH, pCO2 and pO2 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 (cCa2+): 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.
Total Hemoglobin (ctHb): total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.
sO2: oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus reduced hemoglobin.
FO2Hb: 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Date Prepared:
August 5, 2015

Section 5. 510(k) Summary

1. Administrative

Submitter

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2. Device description

Device Information

Device Name:	ABL80 FLEX CO-OX with AQURE connectivity
Common Name:	Blood gas analyzer
Product Code:	CHL (JGS, CEM, JFP, CGZ, CGA, GKR, DQA, GHS, JPI)
Code description:	Blood gases and blood pH test system
Regulation Number:	21 CFR 862.1120
Classification:	Class II
Classification Panel:	Clinical Chemistry

The ABL80 FLEX CO-OX with AQURE connectivity is a portable, automated system intended for in vitro testing of samples of whole blood. The device is manufactured by SenDx Medical Inc, Carlsbad, CA, USA.

ABL80 FLEX CO-OX consists of an instrument with a sensor cassette and a solution pack as the main accessories. Multiple models of sensor cassettes and solution packs are available. The various sensor cassette models include models for the different parameter configurations.

Four measuring principles are employed in ABL80 FLEX analyzers.

- Potentiometry: The potential of a sensor chain is recorded using a voltmeter, and related to the concentration of the sample (the Nernst equation).
- Amperometry: The magnitude of an electrical current flowing through a sensor chain is proportional to the concentration of the substance being oxidized or reduced at an electrode in the chain.
- Conductometry: Specific impedance of a sample as measured by two conducting electrodes held at a constant voltage is directly proportional to the conductive properties of that sample.
- Spectrophotometry: Light passes through a cuvette containing a hemolyzed blood sample. The specific wavelengths absorbed and their intensity generates an absorption spectrum used to calculate oximetry parameters. This measuring principle is used in the ABL80 FLEX CO-OX analyzer only.

3. Device Modification

The modification consists of integration with the Data Management software called AQURE system. The software enables the initiation of device actions on connected ABL80 FLEX analyzers.

4. Intended Use

The ABL80 FLEX CO-OX analyzer is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, and oximetry in whole blood. The ABL80 FLEX CO-OX analyzer 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.

Indications for use:
These tests are only performed under a physicians order:
pH, pO2,and pCO2, : pH, pCO2 and pO2 measurements are used in the diagnosis and treatment of life-threatening acid-base disturbances.
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Calcium (cCa2+): calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.
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Total Hemoglobin (ctHb): total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.
sO2: oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus reduced hemoglobin.
FO2Hb: 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.

5. Substantial Equivalence

The modified ABL80 FLEX CO-OX analyzer is substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate (K080370).

Similarities		
Issue	**SE Device**	**Predicate Device (K080370)**
Intended Use	Same	The ABL80 FLEX CO-OX analyzer is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, and oximetry in whole blood. The ABL80 FLEX CO-OX analyzer 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.
Blood Gas Measurement	Same	pH, pCO_2 by potentiometry, pO_2 by amperometry
Electrolyte Measurement	Same	cK^+, cNa^+, cCa^{2+}, cCl^- by potentiometry
Metabolite Measurement	Same	cGlu by amperometry
Oximetry Measurement	Same	ctHb, sO_2, FO_2Hb, FHHb, FCOHb, FMetHb by spectrophotometry
Performance Characteristics	Same	Identical Performance Characteristics
Calibration	Same	Two-Point liquid calibration at configured intervals, tHb calibration every 90 days
Computer specifications	Same	Microsoft Windows®XP Embedded operating system Minimum 1 GB hard drive ETX single board CPU Minimum 512 MB EDO-RAM
Sample Introduction	Same	Aspiration
Interfaces	Same	8.4” color TFT-LCD, resolution 800 × 600 SVGA Touch screen, Barcode reader, Serial line RS232, RJ45, Ethernet port, 2 USB 1.1, PS2 keyboard
Software version	Same	Software version 3.12

Differences		
Issue	**SE Device**	**Predicate Device (K080370)**
AQURE system	Data management software (MDDS) functionality: • Remote display of test results • Receival of data from connected devices at the point-of-care or laboratory • Transfer of test results to the HIS/LIS • Centralized operator administration – Transmission of operator data to ABL80 FLEX CO-OX • Remote approval of patient results	Analyzer functionalities are: • Local display of test results • Direct transfer of test results to the HIS/LIS • Local Operator Administration at the analyzer
	Remote initiation of the following device actions on ABL80 FLEX CO-OX from AQURE system: • System Cycle • Rinse • Lock/Unlock analyzer • Lock/Unlock parameter • Set analyzer message • Enter/Exit standby • 2 point calibration	Local initiation of device actions through device touch screen interface

6. Registration history

ABL80 FLEX was originally cleared with K051804 (measures pH, blood gases, electrolytes, glucose, hematocrit (ABL80 FLEX analyzer only), and then modified in K080370 with the addition of an oximetry Module - a configuration of the analyzer adding the oximetry parameters ctHb, sO2, and the hemoglobin fractions FO2Hb, FCOHb, FMetHb, and FHHb.

7. Performance Data

Remote functionality was verified and validated on both ABL80 FLEX and ABL80 FLEX CO-OX analyzers, and the acceptance criteria was met.

No performance characteristics are affected by the change. The performance data submitted in the original submission (K051804 as modified by K080370) still apply.

8. Summary of Design Control activities

We conducted an FMEA risk analysis and mitigated all identified hazards to an acceptable level as per ISO 14971, and verified software mitigations by using test protocols. Results met predefined acceptance criteria.

9. Conclusion

The ABL80 FLEX CO-OX with AQURE connectivity described above is substantially equivalent in Intended Use, fundamental scientific technology, safety, effectiveness and characteristics to the predicate ABL80 Flex CO-OX (K080370). Implementation of the change design control principles (risk management, verification and validation) have been applied which indicated that the modification is of no impact to the performance of the device.