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Sincerely yours,

**Katherine Serrano -S**

For: 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

## Indications for Use

510(k) Number (if known)

K151639

Device Name

ABL80 FLEX

ABL80 FLEX CO-OX

Indications for Use (Describe)

The ABL80 FLEX analyzer is a portable, automated analyzer that measures glucose, in whole blood. The ABL80 FLEX 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.

For in vitro diagnostic use.

The ABL80 FLEX CO-OX analyzer is a portable, automated analyzer that measures glucose, 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.

For in vitro diagnostic use.

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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**510(k) Summary****1. Submitter and contact information****Submitter**

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**Date prepared**

Date: December 4, 2015

**2. a. Device Information**

Device Name: ABL80 FLEX and ABL80 FLEX CO-OX analyzer  
Common Name: Blood gases, Cooximetry, and Metabolite analyzer

## Classification:

Classification name	CFR Section	Device Class	Product Code
Glucose oxidase, Glucose	862.1345	II	CGA

## **2. b. Device Description**

### ***Instrument name, manufacturer, models and accessories***

The names of the device are the ABL80 FLEX or ABL80 FLEX CO-OX. The device is manufactured by SenDx Medical Inc, Carlsbad, CA, USA. Radiometer Medical ApS, Brønshøj, Denmark is the legal manufacturer of the device as specified in the labelling.

The ABL80 FLEX and ABL80 FLEX CO-OX analyzers are portable, automated systems intended for in vitro testing of samples of whole blood for the parameters pH, pO<sub>2</sub>, pCO<sub>2</sub>, potassium, sodium, calcium, chloride, glucose, hematocrit (ABL80 FLEX analyzer only) and the oximetry parameters (ABL80 FLEX CO-OX only) total hemoglobin, oxygen saturation, FO<sub>2</sub>Hb, FCOHb, FMetHb, and FHHb.

The ABL80 FLEX and ABL80 FLEX CO-OX analyzers each exist in two different software configurations differing in the number of parameters available.

The ABL80 FLEX and ABL80 FLEX CO-OX analyzers consist of an instrument with a sensor cassette and a solution pack as the main accessories. Multiple models of sensor cassettes are available. The various sensor cassette models include models for different parameter combinations. For each parameter combination, models allowing for different test loads are available. The solution pack is available in four models, one model for each of the four different configurations of the analyzer.

## **2. c. Purpose of submission**

The purpose of this submission is twofold:

- Automated handling by the software of certain glucose results depending on the pO<sub>2</sub> value in the sample.
- To merge the Intended Uses for the analyzers into one common Intended Use statement.

## **3. Intended Use/Indications for use**

The ABL80 FLEX analyzer is a portable, automated analyzer that measures glucose, in whole blood. The ABL80 FLEX 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.

For in vitro diagnostic use.

The ABL80 FLEX CO-OX analyzer is a portable, automated analyzer that measures glucose, 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.

For in vitro diagnostic use.

**4. Predicate device: ABL800 FLEX analyzer (K043218)**  
**Substantial Equivalence**

The modified ABL80 FLEX and ABL80 FLEX CO-OX analyzers are substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate with regards to glucose measurements:

Predicate device: 510(k) Number, Name, Device Manufacturer:  
 K043218, ABL800 FLEX, Radiometer Medical ApS

<b>Similarities</b>		
<b>Issue</b>	<b>SE Device</b>	<b>Predicate Device (K043218)</b>
Product code	Same	CGA
Measuring method	Same	Amperometric
Calibration Method	Same	Two-point liquid calibration
Intended Use	The ABL80 FLEX and ABL80 FLEX CO-OX analyzers are portable, automated analyzers that measure glucose in whole blood.	Same, plus the following parameters: pH, pO <sub>2</sub> , pCO <sub>2</sub> , potassium, sodium, calcium, chloride, glucose, lactate, total bilirubin, and co-oximetry parameters (total hemoglobin, oxygen saturation, and the hemoglobin fractions FO <sub>2</sub> Hb, FCOHb, FMetHb, FHHb and FHbF)
Glucose measuring range	36-180 mg/dL (pO <sub>2</sub> between 20 - 40 mmHg); 36-270 mg/dL (pO <sub>2</sub> ≥ 41 mmHg)	36-270 mg/dL

<b>Differences</b>		
<b>Issue</b>	<b>SE Device</b>	<b>Predicate Device (K043218)</b>
Intended use site	Laboratory and point-of-care.	Laboratory.

## 5. Performance Characteristics

### Glucose pO<sub>2</sub> dependence

A study has been conducted according to CLSI guideline "Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition", EP07-A2 to characterize the impact of, or interference from, limitations on the amounts of oxygen in the sample.

The test results support the glucose linearity ranges shown below and documented in the labeling:

<b>Glucose linearity versus pO<sub>2</sub> level</b>	
pO <sub>2</sub> (mmHg) range	cGlu mg/dL (mmol/L) linearity range
20 - 40	36 - 180 (2 - 10)
≥ 41	36 - 270 (2 - 15)

Software validation has been conducted and documented for the ABL80 FLEX and ABL80 FLEX CO-OX analyzers to automatically handle certain glucose results depending on the pO<sub>2</sub> value in the sample. This will allow to incorporate limitations of reporting glucose results when the pO<sub>2</sub> value of the sample is low.

## 6. Conclusion

Based on the substantial equivalence comparison and the results of the conducted performance evaluations it has been concluded that the modified ABL80 FLEX and ABL80 FLEX CO-OX analyzers are as safe and effective as the predicate device.