DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 28, 2017

RADIOMETER MEDICAL APS
SOEREN BOEGESTRAND
SENIOR REGULATORY AFFAIRS SPECIALIST
AAKANDEVEJ 21,
BROENSHOEJ, DK DK-2700

Re: K170882
Trade/Device Name: ABL90 FLEX, ABL90 FLEX PLUS
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: March 17, 2017
Received: March 24, 2017

Dear Soeren Boegestrand:

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 regulation (21 CFR Part 801), 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" (21CFR 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,

Kellie B. Kelm -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

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)*
K170882

Device Name
ABL90 FLEX and ABL90 FLEX PLUS

Indications for Use *(Describe)*

ABL90 FLEX:

The ABL90 FLEX analyzer is an in vitro diagnostic, portable, automated analyzer that quantitatively measures neonatal bilirubin in heparinized capillary, venous and arterial whole blood.

The ABL90 FLEX analyzer 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.

Bilirubin measurements on the ABL90 FLEX analyzer are intended to aid in assessing the risk of kernicterus in neonates.

ABL90 FLEX PLUS:

The ABL90 FLEX PLUS analyzer is an in vitro diagnostic, portable, automated analyzer that quantitatively measures neonatal bilirubin in heparinized capillary, venous and arterial whole blood.

The ABL90 FLEX PLUS analyzer 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.

Bilirubin measurements on the ABL90 FLEX PLUS analyzer are intended to aid in assessing the risk of kernicterus in neonates.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary - K170882

1. Submitter and contact information

Submitter

Company Name:	Radiometer Medical ApS
ER Number:	3002807968
Address:	Aakandevej 21 2700 Broenshoej Denmark
Phone:	+45 3827 3827
Fax:	+45 3827 2727
Contact person:	Soeren Boegestrand
E-mail:	soren.bogestrand@radiometer.dk

Contact Person

Name:	Soeren Boegestrand
Function:	Senior Regulatory Affairs Specialist
E-mail:	soren.bogestrand@radiometer.dk
Phone:	+45 3827 3852
Fax:	+45 3827 2727

Date prepared

Date: April 28, 2017

2. Device Information

Device Name: ABL90 FLEX and ABL90 FLEX PLUS

Common Name: Bilirubin (total and unbound) in the neonate test system.

Classification:

Classification name	CFR Section	Device Class	Product Code
Bilirubin (total and unbound) in the neonate test system	862.1113	1, reserved	MQM

3. Device Description

Instrument name, manufacturer, models and accessories
The ABL90 FLEX and ABL90 FLEX PLUS analyzers are two models of the same portable, automated system intended for in vitro testing of samples of whole blood for the parameters pH, pO_2, pCO_2, potassium, sodium, calcium, chloride, glucose, lactate, neonatal bilirubin, and co-oximetry parameters (total hemoglobin, oxygen saturation, and the hemoglobin fractions FO_2Hb, *F*COHb, *F*MetHb, *F*HHb and *F*HbF).

The manufacturer of the ABL90 FLEX and ABL90 FLEX PLUS is Radiometer Medical ApS.

The ABL90 FLEX and ABL90 FLEX PLUS 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 load are available.

The solution pack is available in two models differing in the number of tests available.

Technology
The ABL 90 FLEX and ABL90 FLEX PLUS electrochemical sensors are miniaturized, manufactured by film technology and integrated in a common sensor cassette. Likewise, the ABL90 FLEX and ABL90 FLEX PLUS optical oxygen sensor is integrated in the sensor cassette. A 256-pixel array spectrophotometer is used for the co-oximetry parameters and bilirubin.

Clinical Utility ctBil
For newborns up to an age of one month the method's reportable range covers the entire reference range. Neonatal Bilirubin test is intended for use to aid in assessing the risk of kernicterus in newborns.

4. Intended Use/Indications for use

ABL90 FLEX:

The ABL90 FLEX analyzer is an in vitro diagnostic, portable, automated analyzer that quantitatively measures neonatal bilirubin in heparinized capillary, venous and arterial whole blood.

The ABL90 FLEX 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.

Bilirubin measurements on the ABL90 FLEX analyzer are intended to aid in assessing the risk of kernicterus in neonates.

ABL90 FLEX PLUS:

The ABL90 FLEX PLUS analyzer is an in vitro diagnostic, portable, automated analyzer that quantitatively measures neonatal bilirubin in heparinized capillary, venous and arterial whole blood.

The ABL90 FLEX PLUS 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.

Bilirubin measurements on the ABL90 FLEX PLUS analyzer are intended to aid in assessing the risk of kernicterus in neonates.

5. Substantial Equivalence

The ABL90 FLEX and ABL90 FLEX PLUS analyzer with neonatal bilirubin on arterial and venous whole blood is substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate:

510(k) Number/Device Manufacturer:
K050869 ABL800 FLEX, Radiometer Medical ApS

Similarities		
Item	**Candidate Device**	**Predicate Device (K050869)**
Product code	Same	MQM
Measuring method	Same	Spectrophotometrical
Calibration Method	Same	Two-point liquid calibration
Intended use	Same	In vitro testing of whole blood samples for total bilirubin

Differences		
Item	**Candidate Device**	**Predicate Device (K050869)**
Sample types	Heparinized capillary, arterial and venous whole blood	Whole blood
Intended use site	Laboratory and point-of-care.	Laboratory.
Neonatal bilirubin measuring range	µmol/L: 28 – 648 mg/dL: 1.6 – 37.9 mg/L: 16 – 379	µmol/L: 0 – 1000 mg/dL: 0.0 – 58.5 mg/L: 0 – 585

The ABL90 FLEX and ABL90 FLEX PLUS analyzers with neonatal bilirubin on arterial and venous whole blood described above are substantially equivalent in Intended Use, fundamental scientific technology, and characteristics to the predicate ABL800 FLEX (K050869) regarding the measurement of neonatal bilirubin.

6. Performance Characteristics
Substantial equivalence between the ABL90 FLEX PLUS analyzer and ABL90 FLEX analyzer has been demonstrated in K160153.

Verification of the ABL90 FLEX PLUS has demonstrated that the performance of the ABL90 FLEX PLUS is equivalent to the performance of ABL90 FLEX.

Since meaurements conducted on ABL90 FLEX PLUS and ABL90 FLEX are equivalent, the neonatal bilirubin testing on arterial and venous whole blood samples conducted on ABL90 FLEX represent both ABL90 FLEX and ABL90 FLEX PLUS.

The purpose of this submission is to include arterial and venous whole blood sample types to the neonatal bilirubin assay using the ABL90 FLEX and ABL90 FLEX PLUS Analyzers. Precision, linearity, detection limits and analytical specificity performance were previously established in k132691 in support of substantial equivalence for capillary whole blood, and are also applicable for arterial and venous whole blood. Consequently, only method comparison studies have been performed on arterial and venous neonatal whole blood to support substantial equivalence for these sample types.

6.1 Method Comparison
Method comparison study versus the predicate device has been conducted at two point-of-care sites, samples were analyzed by 4 to 5 operators per site. Bilirubin measurements were performed on 44 arterial, 42 venous and 17 spiked cord blood samples.

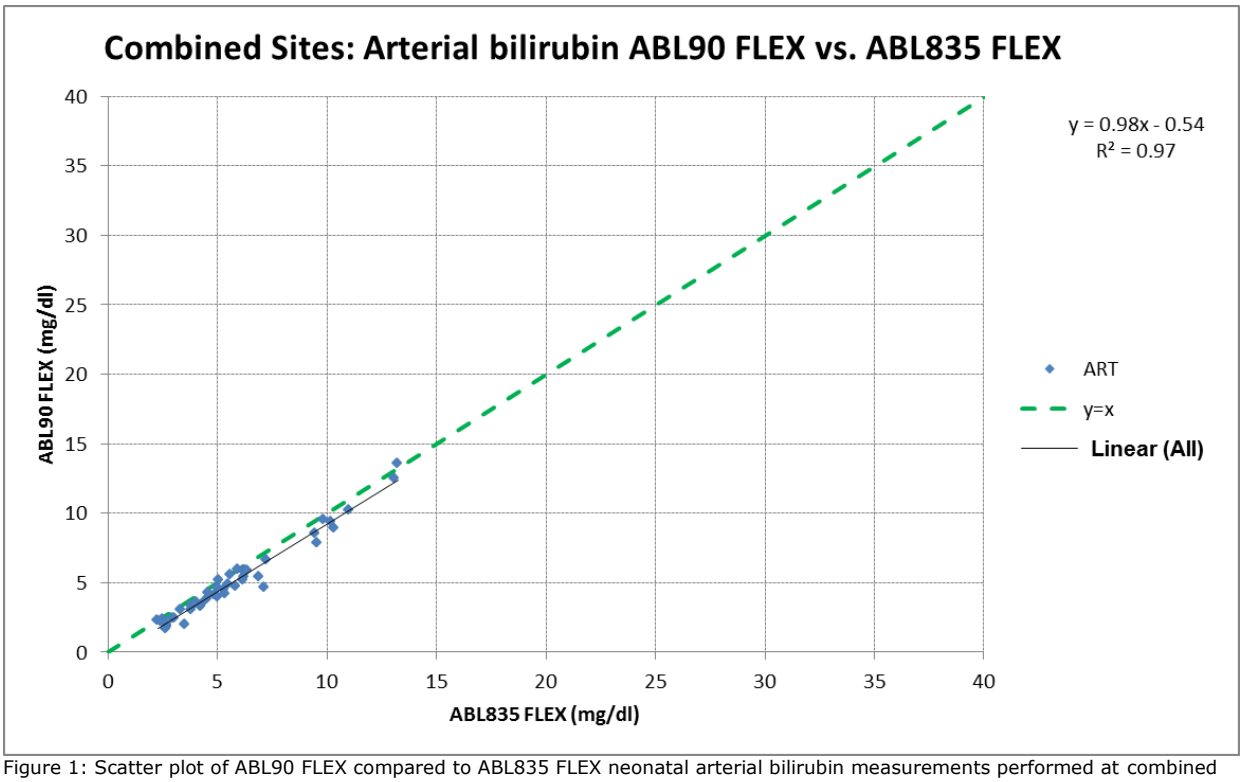

Figure 1: Scatter plot of ABL90 FLEX compared to ABL835 FLEX neonatal arterial bilirubin measurements performed at combined sites. The linear regression line is based on measurements made on arterial blood samples.

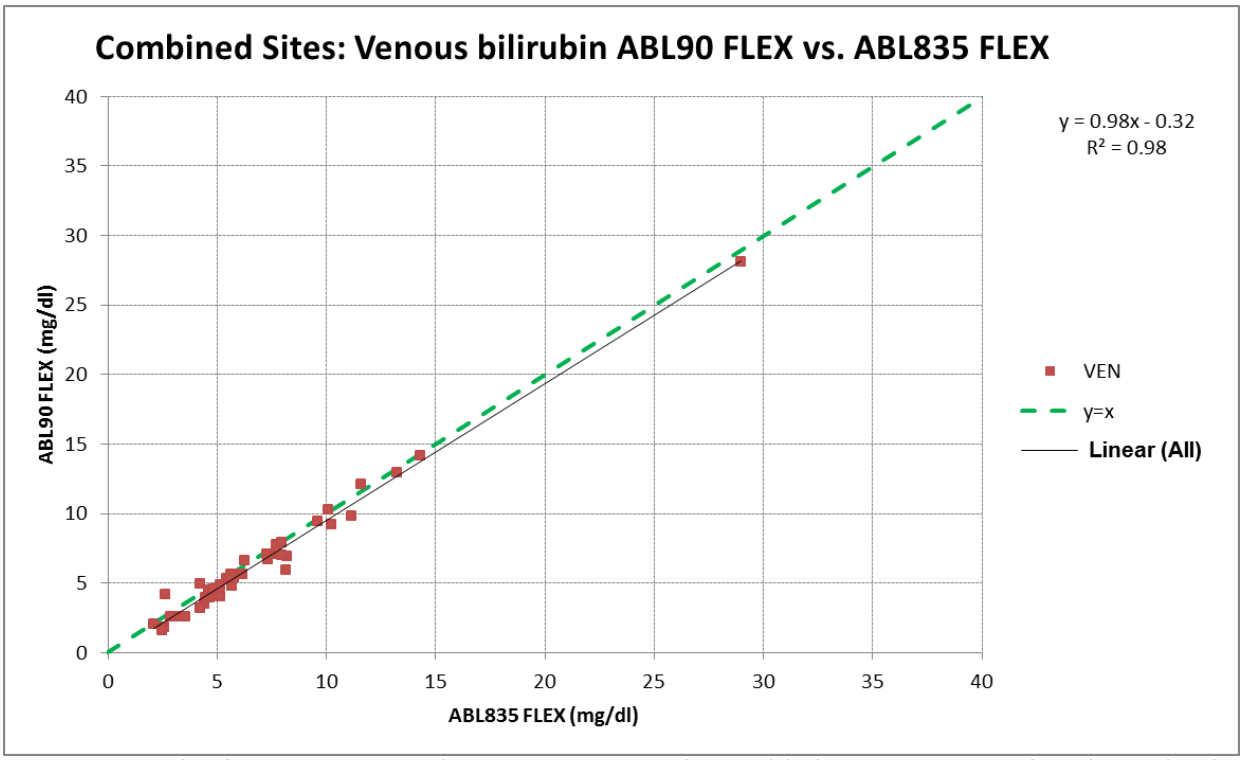

Figure 2: Scatter plot of ABL90 FLEX compared to ABL835 FLEX neonatal venous bilirubin measurements performed at combined sites. The linear regression line is based on measurements made on venous blood samples.

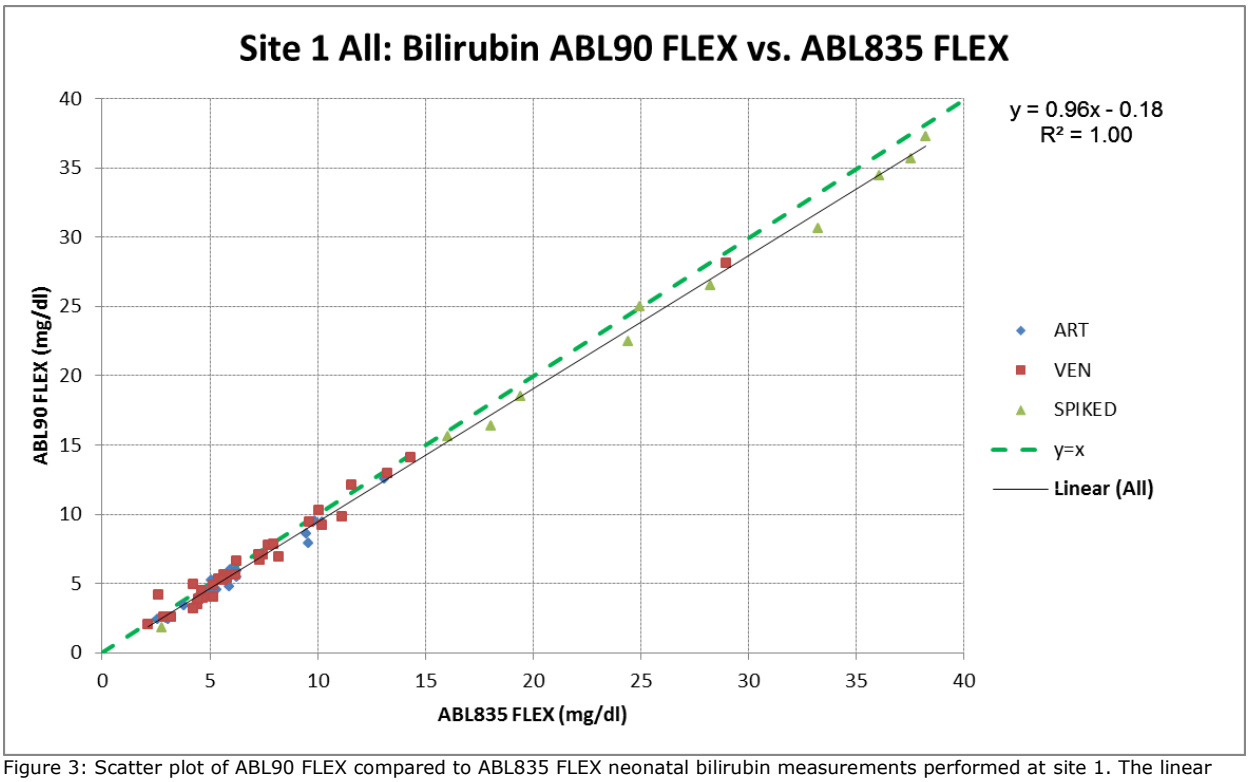

Figure 3: Scatter plot of ABL90 FLEX compared to ABL835 FLEX neonatal bilirubin measurements performed at site 1. The linear regression line is based on measurements made on arterial-, venous- and spiked cord blood samples.

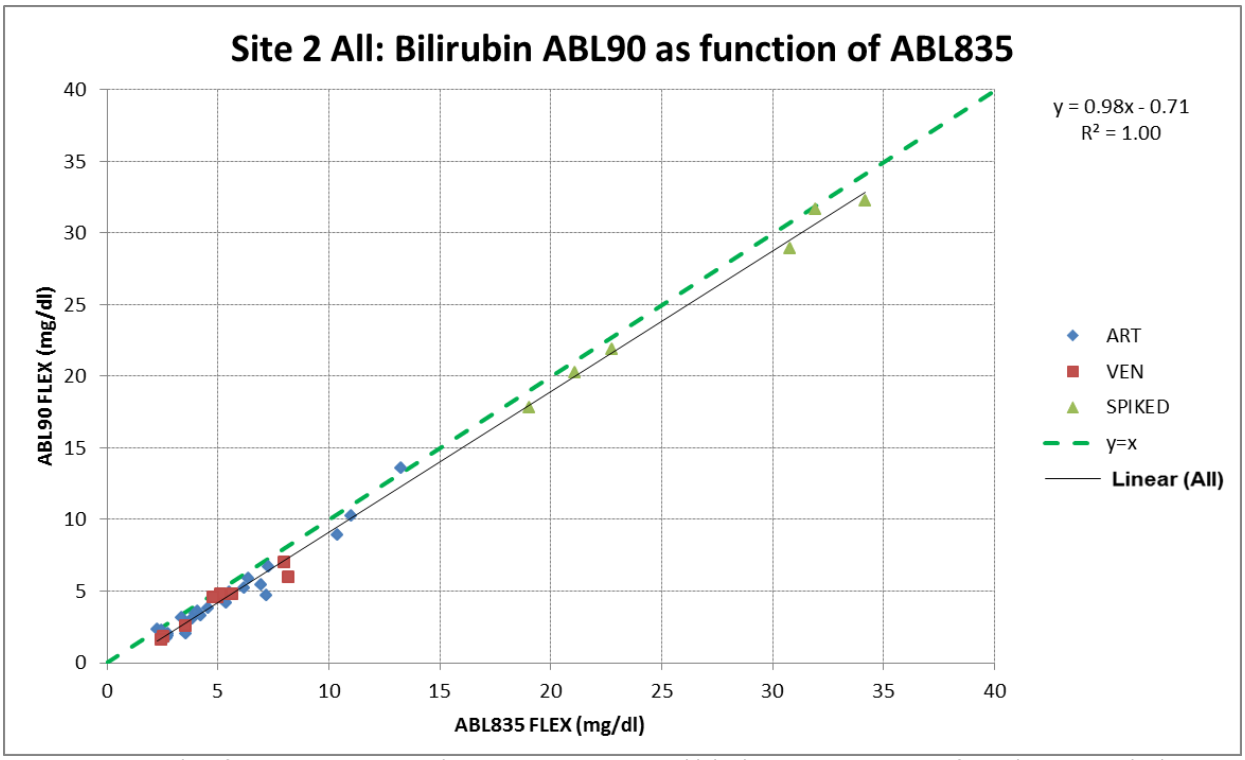

Figure 4: Scatter plot of ABL90 FLEX compared to ABL835 FLEX neonatal bilirubin measurements performed at site 2. The linear regression line is based on measurements made on arterial-, venous- and spiked cord blood samples.

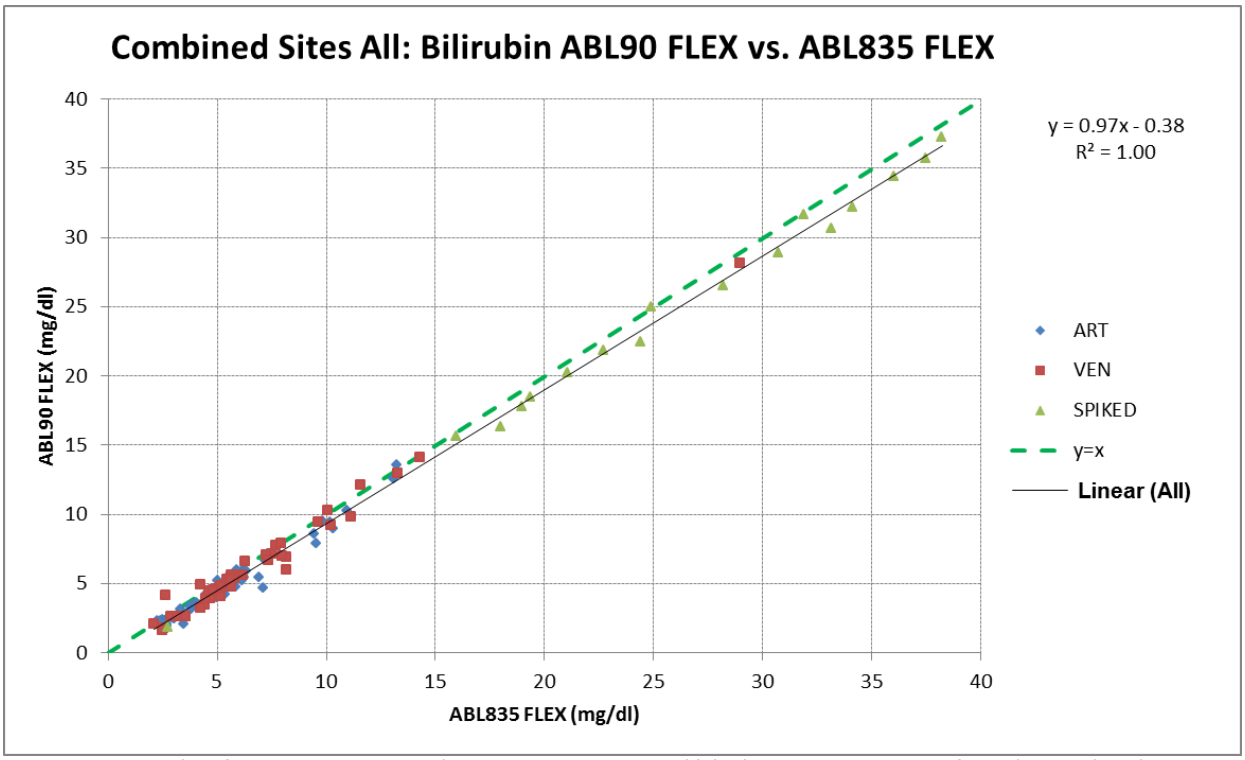

Figure 5: Scatter plot of ABL90 FLEX compared to ABL835 FLEX neonatal bilirubin measurements performed at combined sites. The linear regression line is based on measurements made on arterial-, venous- and spiked cord blood samples.

Parameter	Units	Range Low	Range High	Total n =	Spiked n =	Slope	Intercept	R^2	$S_{y.x}$
*ct*Bil All	mg/dL µM	1.6 27	37.3 638	103	17	0.97	-0.38 -6.50	1.00	0.60 10.3
*ct*Bil Arterial All	mg/dL µM	1.7 30	13.6 232	44	N/A	0.98	-0.54 -9.23	0.97	0.53 9.06
*ct*Bil Venous All	mg/dL µM	1.6 27	28.1 481	42	N/A	0.98	-0.32 -5.47	0.98	0.62 10.6
*ct*Bil site 1	mg/dL µM	1.8 31	37.3 638	66	11	0.96	-0.18 -3.07	1.00	0.57 9.75
*ct*Bil site 2	mg/dL µM	1.6 27	32.2 551	37	6	0.98	-0.71 -12.1	1.00	0.58 9.91

Table 1: Neonatal bilirubin linear regression data for ABL90 FLEX measurements compared to ABL835 FLEX measurements

7. Conclusion

Based on the substantial equivalence comparison and the results of the conducted performance evaluations it has been concluded that the ABL90 FLEX and ABL90 FLEX PLUS with neonatal bilirubin on arterial and venous whole blood are as safe and effective as the predicate device.