epocal

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JUN 24 2009

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K090109.

Summary Prepared: May 21, 2009

Submitted by:
Epocal Inc.
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Contact:
Roy Layer
Director of Quality Assurance and Regulatory Affairs.

5.1 Identification of the Device

Device Name:	Glucose Oxidase, Glucose
Proprietary / Trade Name:	EPOC Glucose Test
Common Name:	Glucose Oxidase, Glucose
Classification Name:	Glucose Test System
Device Classification:	II
Regulation Number:	862.1345
Panel:	Clinical Chemistry
Product Code:	CGA

5.2 Identification of the Predicate Device

i-Stat™ Glucose Test using i-Stat™ Model 300 Portable Clinical Analyzer

5.3 Description of the New Device

The EPOC glucose test is being added as an additional sensor to the existing single use test card that is used with the EPOC Blood Analysis System. This test card is inserted into the EPOC Reader and all analytical steps are performed automatically. Patient and user information may be entered into the mobile computing device (EPOC Host) during the automated analysis cycle.

The EPOC Blood Analysis System is an in vitro analytical system comprising a network of one or more EPOC Readers designed to be used at the point of care (POC). The readers accept an EPOC single use test card containing a group of sensors that perform diagnostic testing on whole blood. The blood test results are transmitted wirelessly to an EPOC Host, which displays and stores the test results.

The EPOC System is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of whole blood.

The test card panel configuration currently includes sensors for Sodium Na, Potassium K, Ionized Calcium iCa, pH, pCO_2, pO_2 and Hematocrit Hct. This submission adds Glucose (Glu) to this list of approved tests.

To perform a blood test, a new test card is inserted into a card reader's card slot with white label face down. When fully inserted, the test card is automatically engaged in the reader.

The card insertion process:

- Brings the cards sensor module into contact with the reader's electrical contact array;
- Brings the card's measurement region, which is the fluidic channel above the sensor array, into thermal contact with the reader's heater assembly for heating the measurement region to 37°C;
- Actuates the opening of the fluidic valve in the card and causes delivery of calibrator fluid from the reservoir to the measurement region.

After calibration, and upon a prompt by the reader (LED visual and audio beep), the user introduces a blood sample for measurement through the blood sample port to the card's measurement region. When sensors are contacted by the blood sample they generate electrical signals proportional to analyte concentrations in the blood sample, which are transmitted wirelessly by the Reader to the EPOC Host. The EPOC Host displays and stores the blood test results.

Changes to the EPOC Blood Analysis System required to introduce the Glucose test include:

- Developing a new Glucose sensor and adding it to the existing EPOC test card, which was already designed to accommodate additional sensors;
- Modifications to the existing EpocHost software application to accommodate the new test;
- Labeling changes including indications for use for the Glucose test.

5.4 Comparison of Technological Characteristics To Predicate Device

	EPOC Blood Analysis System	**i-STAT Model 300**	
510(k) #	To be determined	K001387	**Same / Different**
Item	Device	Predicate	
Intended use	The EPOC Blood Analysis System is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of whole blood using the BGEM (Blood Gas Electrolyte Metabolite) test card panels.	The i-STAT Model 300 Portable Clinical Analyzer is intended to be used by trained medical professionals for use with i-STAT test cartridges and MediSense blood glucose test strips. i-STAT cartridges comprise a variety of clinical chemistry tests and test panels.	same
Where used	hospital	hospital	same
Measured parameters	Gluc	Gluc	same

Sample type	Venous, arterial whole blood	Venous, arterial and capillary whole blood	same
Reportable range	Gluc 20 – 700 mg/dL	Gluc 20 – 700 mg/dL	same
Sample volume	95-125 µL	100µL	same
Test card	Unit-use card with - on-board calibrator in sealed reservoir - an electrochemical multi-sensor array - port for sample introduction - fluid waste chamber	Unit-use cartridge with - on-board calibrator in sealed reservoir - an electrochemical multi-sensor array - port for sample introduction - fluid waste chamber	same
Test card storage	Room temperature until expiry date	Fridge storage until expiry date including max 2 weeks at room temperature	different
Sensor array	A laminated foil sensor module	A micro-fabricated chip-set	different
Tests/sensor components	Glu - glucose oxidase based amperometric peroxide detection	Glu - glucose oxidase based amperometric peroxide detection	same
Analyzer components	Two housings; 1 - The reader comprising - Orifice for test card introduction - electrical connector to card - heater for 37°C operation - mechanical card engagement device for o making electrical contact to card's sensors o for rupture of calibrator reservoir o moving calibrator to sensors o engaging heaters with card - op-amp sensor signal detectors - iQC monitoring devices - Thermal controllers - MUX - A/D - Bluetooth stack for wireless transmission of digitized raw sensor signals to computing device - bar code scanner for acquiring card info - internal electronic reader self-test circuit 2 - The computing device comprising a PDA - microprocessor - memory - color LCD display - keyboard - i/o for communicating test results to other devices - software to control the test and calculate analytical values from raw sensor signals - battery operated with rechargeable batteries via plug in plug-in power supply	A single housing comprising - Orifice for test card introduction - electrical connector to card - heater for 37°C operation - mechanical card engagement device for o making electrical contact to card's sensors o for rupture of calibrator reservoir o moving calibrator to sensors o engaging heaters with card - op-amp sensor signal detectors - iQC monitoring devices - Thermal controllers - MUX - A/D - wire transmission of digitized raw sensor signals to computing subsystem in same housing - n/a - internal and external electronic reader self-test circuit - microprocessor - memory - monochrome LCD display - keyboard - i/o for communicating test results to other devices - software to control the test and calculate analytical values from raw sensor signals - battery operated with rechargeable batteries via external power supply in downloader cradle	different same same same same same same same same same same same same different different different same same different same same same same
Measurement	37°C	37°C	same

temperature			
Measurement sequence	Calibrate test card-introduce sample-measure	Introduce sample-calibrate test cartridge-measure	different
Measurement time	30sec from sample introduction	200 sec from sample introduction	different
Error detection	iQC system to detect user errors iQC system for reader self-check iQC system to detect card non-conformance	iQC system to detect user errors iQC system for reader self-check iQC system to detect card non-conformance	same same same

Figure 5.2 – Table Comparing EPOC Device Performance Characteristics With Predicate Device

The EPOC System has the same intended use and utilizes the same test methodologies as the predicate device. Most of the system components are very similar to the predicate device. Differences between the EPOC device and the predicate device have no significant effect on the safety or effectiveness of the system.

5.5 Summary of Non-Clinical Test Performance in Support of Substantial Equivalence

5.5.1 Aqueous precision

Experiments were performed in-house to demonstrate the precision of the EPOC test methods. The table below shows the results of a twenty day precision study performed on 4 lots using aqueous controls at two levels L1 and L3 for the blood gases, electrolytes and metabolytes.

Glucose [mg/dL]	L1	L3
Mean	241.9	50.2
S_{WR}	4.72	1.1
S_{DD}	2.86	0.43
S_T	5.52	1.18
CV%	2.30%	2.30%

Figure 5.3 – Table – 20 Day Precision Study Data

5.5.2 Blood precision

Experiments were performed in-house to demonstrate the precision of the EPOC glucose sensor. The table below shows the results of a study performed in house on whole blood samples prepared to five concentrations of glucose, using cards from four different lots and testing over 100 cards/blood sample on 50 different readers.

Fluid	Lot	n	avg	SD	YSI	iSTAT	ABL	%CV	S_{WR}	
20	09072-8	4	25.4	1.2	25.4	24.0	26.0	4.8%	2.4 mg/dL	pass
	09096-7	24	22.1	1.2	25.4	24.0	26.0	5.2%	2.4 mg/dL	pass
	09097-7	29	22.7	1.0	25.4	24.0	26.0	4.6%	2.4 mg/dL	pass
	09098-7	45	22.4	1.0	25.4	24.0	26.0	4.4%	2.4 mg/dL	pass
20 Total		102	22.5	1.2	25.4	24.0	26.0	5.4%	2.4 mg/dL	pass
120	09072-8	10	121.5	2.6	124.0	120.0	125.0	2.1%	4%	pass
	09096-7	15	124.0	1.5	124.0	120.0	125.0	1.2%	4%	pass
	09097-7	28	123.6	2.9	124.0	120.0	125.0	2.3%	4%	pass
	09098-7	45	124.1	3.4	124.0	120.0	125.0	2.8%	4%	pass
120 Total		98	123.7	3.0	124.0	120.0	125.0	2.4%	4%	pass
200	09072-8	8	210.0	2.6	217.0	209.0	207.0	1.2%	4%	pass
	09096-7	19	216.5	7.0	217.0	209.0	207.0	3.2%	4%	pass
	09097-7	31	214.3	6.9	217.0	209.0	207.0	3.2%	4%	pass
	09098-7	43	217.9	10.2	217.0	209.0	207.0	4.7%	4%	pass
200 Total		101	215.9	8.5	217.0	209.0	207.0	3.9%	4%	pass
300	09072-8	2	302.1	2.1	305.0	305.0	291.0	0.7%	6%	pass
	09096-7	26	314.4	8.5	305.0	305.0	291.0	2.7%	6%	pass
	09097-7	32	309.2	17.9	305.0	305.0	291.0	5.8%	6%	pass
	09098-7	45	312.5	11.3	305.0	305.0	291.0	3.6%	6%	pass
300 Total		105	311.8	13.1	305.0	305.0	291.0	4.2%	6%	pass
500	09072-8	4	529.7	23.8	559.0	526.0	508.0	4.5%	6%	pass
	09096-7	25	554.2	14.6	559.0	526.0	508.0	2.6%	6%	pass
	09097-7	30	544.8	17.1	559.0	526.0	508.0	3.1%	6%	pass
	09098-7	44	548.9	17.8	559.0	526.0	508.0	3.2%	6%	pass
500 Total		103	548.3	17.6	559.0	526.0	508.0	3.2%	6%	pass

Figure 5.4 – Table – Blood Precision Study Data

5.5.3 Linearity/Reportable Range

This study was performed in-house using blood samples as per CLSI EP6-A recommendations for evaluation of linearity. A total of nine blood samples were prepared starting with two pools of blood, which were evaluated versus in-house reference instruments with traceability to NIST standards. Regression analysis was performed as per CLSI EP6-A. The summary is given in the table in figure 5.5.

	Slope	Intercept	R^2
Glu	0.9996	0.64	0.9989

Figure 5.5 – Table - In House Whole Blood Linearity

5.5.4 Traceability

The EPOC System is calibrated is against methods traceable to NIST standards.

The EPOC System's test card comprises an on-board calibration material, prepared gravimetrically and assayed on reference systems calibrated with traceability to NIST standards.

Calibration verification uses commercially available calibration verification fluids whose concentration values are traceable to NIST standards.

Quality control materials are commercially available fluids with concentrations traceable to NIST standards.

5.5.5 Detection Limit

Detection limits for the EPOC measurements are those determined by the limits of the reportable range.

5.5.6 Effect of Hematocrit

Hematocrit effect was evaluated in six glucose level blood linearity studies performed at four different hematocrit levels.

The hematocrit was evaluated as per CLSI H07-A2 recommendations. The reference mean glucose concentration was computed from the average of at least two in house reference instruments with traceability to NIST standards.

The summary is presented in the Table below:

Hct [PCV]	Glu level	Ref. mean [mg/dL]	EPOC mean [mg/dL]	Mean 95%conf [mg/dL]	EPOC %CV	EPOC bias [mg/dL]
30	35	33.7	34.9	2.1	8.4%	1.2
30	60	54.5	55.6	1.0	2.5%	1.1
30	130	128.7	127.9	1.2	1.3%	-0.7
30	200	209.3	212.6	3.2	2.1%	3.2
30	400	407.2	425.4	7.9	2.6%	18.2
30	600	608.3	601.4	14.8	3.3%	-7.0
43	35	36.6	36.0	1.1	1.2%	-0.6
43	50	49.2	46.4	0.8	3.8%	-2.7
43	100	96.8	95.4	1.8	5.7%	-1.4
43	130	129.9	128.4	2.7	2.2%	-1.5

43	200	204.7	205.3	2.0	2.6%	0.6
43	350	330.7	346.4	10.8	2.4%	15.7
43	650	670.5	690.5	32.4	4.0%	20.0
52	35	34.0	35.9	2.1	5.8%	1.9
52	60	55.7	55.8	1.0	2.7%	0.1
52	130	130.7	129.7	1.2	1.5%	-0.9
52	200	216.0	210.2	3.2	1.3%	-5.8
52	400	416.7	417.3	7.9	2.0%	0.7
52	600	615.2	596.2	14.8	5.1%	-18.9
62	35	29.7	31.6	0.6	2.1%	1.9
62	50	46.8	45.9	0.4	1.2%	-1.0
62	100	95.4	93.9	1.9	1.8%	-1.5
62	130	127.5	121.7	1.3	1.0%	-5.8
62	200	205.1	201.6	3.5	1.3%	-3.4
62	350	326.0	336.0	3.2	2.5%	10.0
62	650	666.0	685.3	9.8	2.2%	19.2

Figure 5.6 – Table – Summary of glucose blood linearity results at various Hct levels

5.5.7 Analytical Specificity

The following tables summarize data from interference studies performed on the EPOC device. The data are presented as interference bias (test result minus control) expressed as a fraction of TE, the total allowable error (or as a % bias, where '%' is indicated).

Exogenous Interference	Interference level	CLSI	Mean (Test result - blank control)/TE
Acetaminophen	1.66 mM	1.6mM	-0.4
N-Acetyl Cysteine	0.5 mM	16.6mM	-0.7
N-Acetyl Cysteine	1 mM	16.6mM	**-12%**
Acetyl Salicylic Acid	3.33 mM	3.33mM	+0.3
Na Ascorbate	630 µM	227µM	+0.2
Bromide	15 mM	37.5mM	-0.6
Bromide	25 mM	37.5mM	**-10%**
CaOxalate	78 mM	-	**-23%**
Citrate	15 mM	-	-0.4
Citrate	20 mM	-	**-8%**
Cyanide	0.1 mM	-	-0.1
Digoxin	6.15 nM	6.15nM	-0.1
Dobutamine	66 µM	-	+0.2
Dopamine HCl	100 µM	5.87µM	-0.4
L-dopa	1 mg/dL	-	-0.4
L-dopa	2 mg/dL	-	**-11%**
Methyldopa	71 µM	71µM	-0.7
EDTA	9 mM	-	-0.6
Ephedrine	12 µM	-	+0.1
Ethanol	87 mM	86.8mM	+0.3
Ethylene Glycol	4.84 mM	4.83mM	0.0
NaFluoride	10 mM	105µM	-0.6
NaFluoride	100 mM	105µM	**-16%**

Fructose	1 mM	-	-0.2
Galactose	3.3 mM	-	+0.4
Gallamine Triethiodide	0.5 mg/dL	-	-0.5
Gallamine Triethiodide	1 mg/dL	-	**-10%**
Gentamicin	100 µg/mL	100µg/mL	+0.1
Glipizide	4.5 µM	4.5µM	+0.1
Glucosamine	1.1 mM	-	0.0
Glutathione oxidized	2.55mmol/L_{RBC}	-	-0.2
Glutathione reduced	2.55mmol/L_{RBC}	-	-0.5
Glycolic Acid	1 mM	-	0.0
Guaiacol	0.4 mM	-	0.1
Heparin	80 U/mL	3 U/mL	-0.3
HydroxyUrea	2.5 mM	-	+0.5
Isoniazide (Nydrazid)	292 µM	292 µM	-0.6
Ibuprofen	2.5 mM	2.425 mM	0.0
Maltose	13.3 mM	-	-0.1
Mannose	3.5 mM	-	+0.4
Mannose	5 mM	-	**+15%**
NaPenthotal	413 µM	248 µM	-0.1
Procainamide	102 µM	102 µM	0.0
Quinidine	37 µM	37 µM	-0.7
Salycilic Acid	4.34 mM	4.34 mM	-0.2
Thiocyanate	1 mM	6.9 mM	-0.7
Thiocyanate	6.9 mM	6.9 mM	**-16%**
Tolazamide (Tolinase)	1 mM	-	-0.3
Tolbutamide	2.37 mM	2.37 mM	+0.1
Xylose	3 mM	-	+0.1
Xylose	4 mM	-	**+8%**

Figure 5.7 – Table of Interference Test Data Expressed as Fraction of Total Allowable Error (TE); Exogenous Interferences for the Glucose Sensor

Endogenous Interference	Interference level	CLSI	Mean (Test result – blank control)/TE
Bilirubin Conj	86 µM	86 µM	0.0
Bilirubin Unconj	513 µM	257 µM	0.0
Cholesterol	7.7 mM	6.47 mM	+0.5
L-Cysteine	0.5 mM	-	-0.4
L-Cysteine	1.5 mM	-	**-31%**
Hydroxy Butyrate	20 mM	-	-0.4
Intralipid	0.8%	-	0.0
Lactate	20 mM	2.6 mM	-0.5
pH Acidic	6.66	-	-0.2
pH Alkaline	7.72	-	-0.3
Norepinephrine	59.2 µM	10.4 nM	0.0
Low Total protein	3.4%	6%	+0.1
High Total Protein	10.4%	8%	-0.1
Triglycerides	500 mg/dL	500 mg/dL	-0.2
Uric Acid	0.5 mM	0.5 mM	-0.6
Uric Acid	1.5 mM	0.5 mM	**-15%**

Figure 5.8 – Table of Interference Test Data Expressed as Fraction of Total Allowable Error (TE); Endogenous Interferences for the Glucose Sensor

5.6 Summary of Clinical Tests Submitted in Support of Substantial Equivalence

5.6.1 Method comparison with predicate device

The method comparison studies were performed in field trials at several hospitals on patient samples of whole blood at various locations. Patient specimens were capillary, arterial and venous. The method comparison was against the predicate device.

	N	Slope	Intercept	Syx	R	X min	X max
Glu	160	1.022	-2.338	5.4	0.999	20.0	605.5

Figure 5.9 – Table of Method Comparison Summary against Predicate Device

5.6.2 Matrix effects

5.6.2.1 Effect of anticoagulant

The effect of anticoagulant was evaluated on patient samples that were collected using heparinized and non-heparinized collection devices. This study was performed at various POC sites of a hospital. The data was analyzed using EP9-2A methodology. The table in figure 5.10 shows the method comparison summary versus the predicate device.

Glucose [mg/dL]	Heparinized	Unheparinized	All
N	29	29	58
Sxx	1.22	1.07	1.14
Syy	3.24	3.00	3.12
intercept	2.0	-0.7	0.7
slope	0.994	1.019	1.006
Syx	4.94	4.21	4.57
X min	77.5	65	65
X max	266.5	268.5	268.5
R^2	0.9917	0.9939	0.9926

Figure 5.10 – Table of Method Comparison Summary against Predicate Device

5.6.2.2 Venous versus Arterial Blood

Clinical data from method comparison studies performed in field trials at several hospitals and POC locations, on patient samples of whole blood, were analyzed separately as arterial and venous. The data was analyzed using EP9-2A methodology. The table in figure 5.11 shows the method comparison summary vs the predicate device.

Glucose [mg/dL]	Arterial	Venous	All
N	100	114	214
Sxx	1.02	2.76	2.1
Syy	3.33	4.00	3.7

intercept	1.89	-3.03	-1.874
slope	0.991	1.028	1.020
Syx	4.45	5.55	5.2
X min	26	20	20.0
X max	355.0	605.5	605.5
R^2	0.9945	0.9977	0.9969

Figure 5.11 – Table of Method Comparison Summary against Predicate Device

5.6.2.3 Effect of Altitude

A method comparison study was performed at an altitude of over 2000m (~6600 ft) against ABL800 Flex Radiometer whole blood instrument. The data was analyzed using EP9-2A methodology. The table in figure 5.12 shows the method comparison summary.

Glucose	26-100 mg/dL	100-300 mg/dL	300-631 mg/dL	26-631 mg/dL
N	39	26	16	81
Sxx	2.2	4.3	22.9	10.6
Syy	1.3	4.4	13.6	6.6
intercept	-1.9	-4.1	-5.9	-6.12
slope	0.986	1.009	1.032	1.031
Syx	2.8	8.0	17.1	8.8
X min	26.0	99.5	301.0	26
X max	97	290	631.5	631.5
R^2	0.975	0.985	0.978	0.9976

Figure 5.12 – Table – Method Comparison Summary vs ABL800Flex

5.7 Summary of Conclusions Drawn from Non Clinical and Clinical Tests

We conclude from the data presented in section 5.5 that the device performs effectively. We conclude from the data section 5.6 that the clinical performance of the device is equivalent to the predicate device: i-Stat Model 300 Portable Clinical Analyzer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 24 2009

Epocal, Inc.
c/o Roy Layer
Director Quality Assurance & Regulatory Affairs
2060 Walkley Rd.
Ottawa, Ontario, CA K1G-3P5

Re: k090109
Trade/Device Name: Blood Gas, Electrolyte And Metabolite Test Card
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II
Product Code: CGA
Dated: June, 16, 2009
Received: June 17, 2009

Dear: Mr. Layer:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting 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: k090109

Device Name: epoc Glucose test

Indication For Use:

The Glucose test, as part of the epoc Blood Analysis System is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial or venous whole blood in the laboratory or at the point of care in hospitals, nursing homes or other clinical care institutions.

Glucose measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, and idiopathic hypoglycemia, and of pancreatic islet cell tumors.

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)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K090109