K061597

APPENDIX 9

epocal

SEP 27 2006

2935 Conroy Road
Ottawa Ontario, Canada K1G 6C6

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: _____ .

Summary Prepared: June 7, 2006

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:	EPOC™ Blood Analysis System
Proprietary / Trade Name:	EPOC Blood Analysis System
Common Name:	Portable Blood Analyzer
Classification Name:	See Tables Below
Device Classification:	See Tables Below
Regulation Number:	See Tables Below
Panel:	See Tables Below
Product Code:	See Tables Below

Name	Class	Regulation Number	Panel	Product Code
Electrode, Ion Specific, Sodium	II	862.1665	Clinical Chemistry	JGS
Electrode, Ion Specific, Potassium	II	862.1600	Clinical Chemistry	CEM
Hematocrit	II	864.6400	Hematology	JPI
Electrode, Ion Specific, Calcium	II	862.1145	Clinical Chemistry	JFP
Electrode Measurement, Blood-Gases (PCO2, PO2) and Blood pH	II	862.1120	Clinical Chemistry	CHL

Figure 5.1 – Table - EPOC™ Blood Analysis System with Blood Gas Electrolyte (BGE) Test Card

5.2 Identification of the Predicate Device

i-Stat™ Model 300 Portable Clinical Analyzer

5.3 Description of the New Device

The EPOC system is a new device that has never been marketed in the United States of America. There are no previous related 510k submissions for this device.

The EPOC Blood Analysis System consists of three (3) components:

1. EPOC Test Card
   The single use blood test card comprises a port for introduction of a blood sample to an array of sensors on a sensor module. The sensor module is mounted proximal to a fluidic channel contained in a credit-card sized housing. The card has an on-board calibrator contained in a sealed reservoir fluidically connected to the senor array through a valve.

2. EPOC Card Reader
   The reader is a minimally featured raw-signal acquisition peripheral. The reader comprises a card orifice for accepting a test card, and a mechanical actuation assembly for engaging the test card after it is inserted into the card orifice. Within the reader's card orifice there is a bar code scanner, an electrical contact array for contacting the card's sensor module, and a thermal subsystem for heating the card's measurement region to 37°C during the test. The reader also comprises circuits for amplifying, digitizing and converting the raw sensor signals to a wireless transmittable Bluetooth™ format,

3. EPOC Host
   The host is a dedicated use Personal Digital Assistant (PDA) computing device with custom software that displays the test results. The reader and host computer together constitute all of the subsystems generally found in a traditional analyzer that operates on unit-use sensors and reagents

5.4 Intended Use of the Device

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 in the laboratory or at the point of care in hospitals, nursing homes or other clinical care institutions.

The BGE test card panel configuration includes sensors for Sodium Na, Potassium K, Ionized Calcium iCa, pH, pCO_2, pO_2 and Hematocrit Hct.

Measurement of sodium and potassium are used in diagnosis and treatment of diseases involving electrolyte imbalance. Measurement of ionized calcium is used in diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany. Measurement of pH, pCO_2 and pO_2 (blood gases) is used in the diagnosis and treatment of life-threatening acid-base disturbances. Measurement of hematocrit distinguishes normal from abnormal states of blood red cell volume, such as in anemia and erythrocytosis

5.5 Comparison of Technological Characteristics To Predicate Device

	EPOC Blood Analysis System			i-STAT Model 300			Same / Different
510(k) #	To be determined			K001387			
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 BGE (Blood Gas Electrolyte) and ABG (Arterial Blood Gas) 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	pH, pCO_2, pO_2, Na, K, iCa, Hct			pH, pCO_2, pO_2, Na, K, iCa, Hct			same
Calculated parameters	TCO_2, HCO_3,BE,sO_2,Hgb			TCO_2, HCO_3,BE,sO_2,Hgb			same
Sample type	Venous, arterial whole blood			Venous, arterial and skin puncture whole blood			same
Reportable ranges	pH	6.5 – 8.0	pH units	pH	6.5 – 8.2	pH units	different
	pCO_2	5 – 250	mm Hg	pCO_2	5 – 130	mm Hg	different
	pO_2	5 – 750	mm Hg	pO_2	5 – 800	mm Hg	same
	Na	85 – 180	mmol/L	Na	100 – 180	mmol/L	different
	K	1.5 – 12	mmol/L	K	2.0 – 9.0	mmol/L	different
	iCa	0.25 – 4	mmol/L	iCa	0.25 – 2.5	mmol/L	different
	Hct	10 – 75	%PCV	Hct	10 – 75	%PCV	same
	TCO_2	1 – 85	mmol/L	TCO_2	5 - 50	mmol/L	different
	HCO_3	1 – 85	mmol/L	HCO_3	1 – 85	mmol/L	same
	BE_{ecf}	-30 - +30	mmol/L	BE_{ecf}	-30 - +30	mmol/L	same
	BE_b	-30 - +30	mmol/L	BE_b	-30 - +30	mmol/L	same
	sO_2	0 – 100	%	sO_2	0 – 100	%	same
	Hb	3.3 – 25	g/dL	Hb	3 – 26	g/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	pH - PVC ion selective electrode pCO2 - QH modified Severinghaus type pO2 – membrane coated gold cathode Na - PVC ion selective electrode K - PVC ion selective electrode iCa - PVC ion selective electrode Hct – conductivity, gold electrodes			pH - PVC ion selective electrode pCO2 - QH modified Severinghaus type pO2 – membrane coated gold cathode Na - PVC ion selective electrode K - PVC ion selective electrode iCa - PVC ion selective electrode Hct – conductivity, gold electrodes			same same same same same same 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			A single housing comprising - Orifice for test card introduction - electrical connector to card - heater for 37°C operation - mechanical card engagement device for			different same same same

	○ making electrical contact to card's sensors ○ for rupture of calibrator reservoir ○ moving calibrator to sensors ○ 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	○ making electrical contact to card's sensors ○ for rupture of calibrator reservoir ○ moving calibrator to sensors ○ 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	same same same same same same same same same different different same same different same same same same
Measurement temperature	37°C	37°C	same
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.

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

5.6.1 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 using aqueous controls at two levels L1 and L3 for the blood gases and electrolytes, and two levels of aqueous controls for Hematocrit, level A, level B.

	L1						
	pH	***p*CO$_2$**	***p*O$_2$**	**Na**	**K**	**iCa**	**Hct**
Mean	6.986	80.6	78.4	114.5	2.15	2.2	-16.9
S_{WR}	0.006	1.94	1.94	0.57	0.021	0.023	0.35
$\%CV_{WR}$	0.09%	2.40%	2.47%	0.50%	0.97%	1.02%	
S_{DD}	0.004	1.31	1.96	0.67	0.011	0.017	0.42
$\%CV_{DD}$	0.05%	1.63%	2.50%	0.59%	0.51%	0.76%	
S_T	0.008	2.36	2.57	0.80	0.025	0.028	0.49
$\%CV_T$	0.11%	2.92%	3.28%	0.70%	1.15%	1.26%	

	L3						
	pH	***p*CO$_2$**	***p*O$_2$**	**Na**	**K**	**iCa**	**Hct**
Mean	7.676	22.5	141.2	153.2	6.58	0.67	-14.5
S_{WR}	0.005	0.36	1.78	0.71	0.053	0.009	0.36
$\%CV_{WR}$	0.06%	1.61%	1.26%	0.47%	0.80%	1.29%	
S_{DD}	0.004	0.55	1.44	0.77	0.037	0.010	0.33
$\%CV_{DD}$	0.05%	2.44%	1.02%	0.50%	0.56%	1.43%	
S_T	0.006	0.56	2.24	0.97	0.064	0.012	0.46
$\%CV_T$	0.08%	2.50%	1.58%	0.63%	0.98%	1.77%	

	Level A	Level B
	Hct	**Hct**
Mean	25.3	46.1
S_{WR}	0.370	0.68
$\%CV_T$	1.46%	1.48%
S_{DD}	0.160	0.00
$\%CV_T$	0.63%	0.00%
S_T	0.400	0.68
$\%CV_T$	1.58%	1.48%

Figure 5.3A – Table – 20 Day Precision Study Data

Experiments were performed at three point of care sites with 7 point of care operators performing n=10 replicates on whole blood

In field trials, 10 replicates of different whole blood patient samples were run by different operators of the EPOC system at different point-of-care sites. Each precision study employed 5 different EPOC readers.

Na		mean	SD	% CV
Site 1	operator 1	142	0.5	0.3
	operator 2	143	1.5	1.0
Site 2	operator 3	142	1.2	0.8
	operator 4	143	0.8	0.6
	operator 5	143	0.7	0.5
Site 3	operator 6	141	0.7	0.5
	operator 7	140	1.0	0.7

K		mean	SD	% CV
Site 1	operator 1	4.0	0.05	1.3
	operator 2	4.0	0.00	0.0
Site 2	operator 3	3.7	0.00	0.0
	operator 4	3.8	0.03	0.8
	operator 5	3.7	0.03	0.9
Site 3	operator 6	3.6	0.03	0.9
	operator 7	4.1	0.05	1.2

iCa		mean	SD	% CV
Site 1	operator 1	1.20	0.02	1.5
	operator 2	1.21	0.02	1.9
Site 2	operator 3	1.19	0.02	1.7
	operator 4	1.21	0.03	2.1
	operator 5	1.20	0.02	1.6
Site 3	operator 6	1.23	0.02	1.8
	operator 7	1.24	0.02	1.9

Hct		mean	SD	% CV
Site 1	operator 1	40	0.6	1.4
	operator 2	40	0.5	1.3
Site 2	operator 3	39	0.6	1.6
	operator 4	41	0.5	1.2
	operator 5	40	0.6	1.4
Site 3	operator 6	40	0.8	2.0
	operator 7	38	0.7	1.9

pH		mean	SD	% CV
Site 1	operator 1	7.365	0.006	0.08
	operator 2	7.368	0.005	0.07
Site 2	operator 3	7.322	0.005	0.07
	operator 4	7.335	0.006	0.08
	operator 5	7.303	0.009	0.12
Site 3	operator 6	7.266	0.006	0.08
	operator 7	7.381	0.004	0.05

pCO_2		mean	SD	% CV
Site 1	operator 1	52.3	2.0	3.8
	operator 2	49.9	0.9	1.9
Site 2	operator 3	56.9	0.9	1.5
	operator 4	55.4	1.4	2.5
	operator 5	58.9	1.1	1.9
Site 3	operator 6	61.7	1.8	2.9
	operator 7	41.5	0.9	2.1

pO_2		mean	SD	% CV
Site 1	operator 1	28.6	1.7	6.0
	operator 2	32.9	1.8	5.5
Site 2	operator 3	33.9	1.2	3.5
	operator 4	30.0	1.5	5.0
	operator 5	40.1	1.2	3.1
Site 3	operator 6	61.8	3.5	5.6
	operator 7	74.6	2.9	3.9

Figure 5.3B Field trial whole blood precision at point of care sites

5.6.2 Linearity/Reportable Range

This study was performed in-house to demonstrate linearity on whole blood versus an in-house standard method with traceability to NIST standards.

	Test range	Units	Slope	Intercept	R^2
pH	6.4-7.9	pH units	1.021	-0.15	0.998
pCO_2	10-230	mm Hg	1.058	-3.6	0.998
pO_2	10-750	mm Hg	1.022	-3.9	0.999
K	1.5-12	mmol/L	1.006	0.03	0.999
Na	80-190	mmol/L	0.973	3.8	0.999
iCa	0.6-3.7	mmol/L	1.017	-0.01	0.998
Hct	0-75	% PCV	1.005	-0.58	0.999

Figure 5.4 – Table - In House Whole Blood Linearity

5.6.3 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.

5.6.4 Detection Limit

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

5.6.5 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 indicated).

Exogenous Interference	Level	Mean(Test result - blank control)/TE						
		pH	pCO_2	pO_2	K	Na	iCa	Hct
Ethanol	447 mg/dL	-0.4	-0.2	0.0	+0.1	+0.1	0.0	+0.3
Sodium pentothal	1 mmol/L	0.0	+0.1	-0.2	+0.1	+0.2	-0.4	+0.1
Acetyl salicylate	4.3 mmol/L	0.0	-0.1	-0.1	0.0	0.0	-0.4	+0.2
Ascorbate	0.4 mmol/L	+0.1	-0.3	+0.2	0.0	0.0	0.0	+0.1
Salycilate	4.3 mmol/L	+0.3	0.0	-0.2	+0.1	0.0	-0.4	-0.1
Bromide	18 mmol/L	-0.6	+7%	+0.3	+0.1	+0.3	+0.3	-0.3
Bromide	37.5 mmol/L	-1.2	+13%	+0.0	+0.2	+0.6	+0.9	X
Iodide	1 mmol/L	-0.5	5%	-0.1	+0.0	+0.1	+0.3	-0.1
Iodide	3 mmol/L	-1.2	11%	-0.2	+0.2	+0.0	+0.3	X
Ibuprofen	2.2 mmol/L	-0.3	+0.1	-0.1	0.0	-0.1	-0.3	+0.1
Tylenol	1.66 mmol/L	0.0	-0.1	0.0	0.0	0.0	0.0	X
Ammonium	2 mmol/L	+0.1	-0.2	-0.1	0.0	0.0	-0.1	X
Lithium	4 mmol/L	-0.1	-0.1	0.0	+0.1	0.0	+0.1	-0.1
Halothane	2.7%	X	X	0.0	X	X	X	X

Figure 5.5 – Table Of Interference Test Data Expressed As Fraction Of Total Allowable Error (TE); Exogenous Interferences

Endogenous interference	Level	Mean(Test result - blank control)/TE						
		pH	pCO_2	pO_2	K	Na	iCa	Hct
NaCl	20 mmol/L	-0.3	+0.1	-0.1	+0.1	X	+0.1	X
KCl	8 mmol/L	+0.2	0.0	0.0	X	+0.1	-0.4	X
$CaCl_2$	3 mmol/L	+0.1	+0.3	-0.3	+0.1	+0.4	X	X
pH pCO_2	+/-0.4 pH -/+60 mm Hg	X	X	0.0	0.0	+0.1	-/+0.3	X
Bicarbonate	20 mmol/L	+0.5	+0.3	-0.3	0.1	+0.1	+0.1	X
Lactate	10 mmol/L	+0.2	+0.1	+0.0	-0.1	-0.3	-0.3	X
Hct	+20% PCV		-0.1	+0.1	0.0	-0.5	-0.5	X
Total Protein	+3 g/dL	-0.1	-0.1	+0.1	-0.1	-0.5	-0.5	+0.8
Lipids	0.8%	+0.0	+0.2	+0.1	+0.1	+0.0	+0.2	+0.1
Cholesterol	9.1 mmol/L	0.0	+0.1	0.0	0.0	0.0	0.0	+0.3
Hydroxy butyrate	20 mmol/L	+0.4	-0.2	+0.1	-0.1	-0.7	-0.6	-0.7
Cysteine	1 mmol/L	-0.2	+0.2	0.0	0.0	0.0	0.0	-0.1
Bilirubin	0.26 mmol/L	+0.1	+0.2	-0.1	0.0	+0.1	-0.2	+0.1
NH_4	2 mmol/L	-0.3	-0.3	+0.5	-0.1	0.0	-0.1	-0.1
Phosphate	2 mmol/L	X	X	X	-0.1	0.0	-0.5	-0.3

Figure 5.6 – Table Of Interference Test Data Expressed As Fraction Of Total Allowable Error (TE); Endogenous Interferences

5.7 Summary of Clinical Tests Submitted in Support of Substantial Equivalence

5.7.1 Method comparison with predicate device

The method comparison studies were performed in a field trial at a hospital on patient sample of whole blood at the point of care in the intensive care unit, the cardiac intensive care unit, the hematology/oncology department and in the central lab. Patient specimens were arterial, venous and mixed venous/arterial. The method comparison was against the predicate device.

	N	Slope	Intercept	Syx	R	X min	X max
pH	149	0.966	0.251	0.02	0.991	6.770	7.982
pCO_2	143	1.041	-0.9	2.4	0.990	19.7	112.2
pO_2	142	1.053	-1.7	6.6	0.978	26.0	226.5
K	146	1.013	-0.02	0.09	0.993	2.5	7.8
Na	156	1.077	-9.6	2.2	0.953	123	179
iCa	156	1.021	-0.03	0.031	0.985	0.8	2.2
Hct	142	1.066	-1.1	1.36	0.987	19	73

Figure 5.7 – Table - Method Comparison Summary

5.8 Summary of Conclusions Drawn from Non Clinical and Clinical Tests

We conclude from the data presented in section 5.6 that the device performs effectively. We conclude from the data section 5.7 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

SEP 27 2006

Mr. Roy Layer
Director of Quality Assurance and Regulatory Affairs
Epocal, Inc.
2935 Conroy Road
Ottawa, Canada K1G 6C6

Re: k061597
Trade/Device Name: EPOC™ Blood Analysis System
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (pCO_2, pO_2) and blood pH test system
Regulatory Class: Class II
Product Code: CHL, CEM, JFP, JPI, JGS
Dated: August 19, 2006
Received: August 22 , 2006

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); 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) 276-0484. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

APPENDIX 10

Indications for Use

510(k) Number (if known): K061597

Device Name: EPOC™ Blood Analysis System

Indications For 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 in the laboratory or at the point of care in hospitals, nursing homes or other clinical care institutions.

The Blood Gas Electrolyte (BGE) test card panel configuration includes sensors for Sodium - Na, Potassium - K, ionized Calcium - iCa, pH, pCO2, pO2 and Hematocrit - Hct.

Measurement of Sodium and Potassium are used in diagnosis and treatment diseases involving electrolyte imbalance. Measurement of Ionized Calcium is used in diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany. Measurement of ph pCO2, p02 (blood gases) is used in the diagnosis and treatment of life-threatening acid-base disturbances. Measurement Hct distinguish normal from abnormal states of blood volume, such as anemia and erythrocytosis.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K061597