

15973742

SenDx Medical, Inc.
1945 Palomar Oaks Way
Carlsbad, California 92009
Phone: 760.930.6300
Fax: 760.930.6320

DEC - 3 1997

Company Name: SenDx Medical, Inc.
Address: 1945 Palomar Oaks Way
Carlsbad, California 92009
Phone: 760.930.6300
Fax: 760.930.6320
Contact Person: Ruben Chairez
Date: September 15, 1997

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: _____

14-002

A. Device Proprietary name: **SenDx 100 Blood Gas and Electrolyte Analysis System**

B. Device common name: **Blood Gas and Electrolyte Analyzer**

C. Device classification name:

- 21 CFR 862.1120: **Blood gases (CO₂, pO₂) and blood pH test system
Class II**
- 21 CFR 862.1665 **Sodium test system
Class II**
- 21 CFR 862.1600 **Potassium test system
Class II**
- 21 CFR 862.1145 **Calcium test system
Class II**
- 21 CFR 862.1170 **Electrode, Ion-Specific, Chloride
Class II**
- 21 CFR 864.6400 **Hematocrit measuring device
Class II**

Statement of Substantial Equivalence

The SenDx 100 pH, Blood Gas and Electrolyte Analysis System is substantially equivalent to other blood gas, electrolyte and hematocrit measuring systems used with whole blood.

This 510(k) submission seeks clearance for modifications to the SenDx 100 line as embodied in the two models SD 100B and SD 100IB. These modifications include:

1. Addition of chloride to the electrolyte panel.
2. Modification to the Performance Characteristics section of the Operators Manual.

The SenDx 100 (Model SD100B and SD100IB) is substantially equivalent to other blood gas analyzers such as:

StatPal versions were previously submitted and cleared for marketing under 510(k) document Control numbers:

K903965/B
K914560
K922631/B.

These three StatPal versions were found by FDA to be substantially equivalent to the Mallinckrodt® GEM®-STAT, among other instruments.

The SenDx 100 system was originally submitted and cleared for marketing under Document Control number K954482. This SenDx 100 system was also found by FDA to be substantially equivalent to the Mallinckrodt® GEM®-PREMIER among other instruments.

The SenDx 100 is substantially equivalent to other blood gas and electrolyte systems such as:

- 1) The Ciba-Corning, Corning 865 Blood Gas and Electrolyte System 510(k) Document Control number K 934907.
- 2) The Mallinckrodt® GEM®-PREMIER Blood Gas and Electrolyte Monitor, 510(k) Document Control number K 910305.
- 3) The NOVA Biomedical, NOVA STAT Profile 5, 510(k) Document Control Number K874832.

Description

The SenDx 100™ system consists of the analyzer, a multi-use, disposable sensor cassette and a calibration solution pack. A bar code label containing lot and sensor-specific identifying parameters accompanies each new sensor cassette and calibration solution pack.

The SenDx 100™ line is available in two versions:

Model SD 100 B with modem

Model SD 100 IB without modem for international use

The SD100B is sold in the United States and is UL certified. The unit is battery powered and requires an external battery charger that is provided by SenDx Medical, Inc. Use only Jerome Industries power supply model WSZ118M which requires 100 to 250 VAC, 50 to 60 Hertz with these units. It also has a modem.

The SD100IB is sold internationally and is certified by TUV Rheinland. This unit is also battery powered and requires an external battery charger that is provided by SenDx Medical, Inc. Use only Advance Power Solutions power supply model AD-740U-1180 which requires 100 to 240 VAC, 50 to 60 Hertz with these units. This model is not equipped with a modem.

The SenDx 100™ analyzer utilizes microprocessor controlled electronics. The microprocessor controls the touch screen display, the analog electronics for processing sensor output, and the integral thermal printer. The printer provides a hard copy of the measured and calculated values. Samples are introduced into the analyzer via an aspiration stylus.

The SenDx 100™ sensor incorporates microelectrode technology for the measurement of blood oxygen (pO_2), carbon dioxide (pCO_2), pH, sodium (Na^+), potassium (K^+), chloride (Cl^-), ionized calcium (iCa^{++}), and hematocrit (Hct) in a multi-use, disposable cassette assembly.

The sensors are analogous to traditional electrode methodologies for the measurement of blood gases and electrolytes. A Clark cell for pO_2 measurement and potentiometric ion-selective electrodes for the measurement of pH, pCO_2 , Na^+ , K^+ , Cl^- and iCa^{++} have been miniaturized for placement on a 1-3/8" x 3/8" sensing "chip". Hematocrit is measured by using conductivity.

The sensors are contained in a low volume flow-through cell. The sensor cassette contains reference electrodes for the potentiometric sensors and an integral temperature sensor and heating element for precise temperature control. Calibration and analysis are carried out at 37.0°C. The SenDx 100™ analyzer allows for patient temperature correction over the range of 12-45°C.

All SenDx 100™ sensor cassettes are 100% tested at the factory with multiple precision reference solutions.

Calibration of the system is accomplished using a calibration solution pack which contains two levels of precision tonometered electrolyte solutions packaged in gas tight disposable cartridges. Precise pH, blood gas, and electrolyte calibration values for each pack are provided on an attached calibration bar code label.

The SenDx 100™ performs two point calibrations at automatic intervals. Throughout the calibration and sample analysis phases, sensor signals are continuously monitored. If any abnormal conditions are detected, an error message is generated.

Blood analysis and the subsequent system calibration and flush take approximately 50-75 seconds. After analysis, pH, $p\text{CO}_2$, $p\text{O}_2$, Na^+ , K^+ , Cl^- , $i\text{Ca}^{++}$, and Hct measurement results are displayed on the analyzer touch screen. The measured values and derived values (HCO_3^- , BEb, BEecf, TCO_2 , SBC, Hb, and % O_2 Sat) are automatically printed.

The SenDx 100™ system can be interfaced via the RS232 serial data port with PC based or LIS/HIS data management systems.

Intended Use

The SenDx 100™ pH, Blood Gas and Electrolyte Analysis System (SenDx 100™) is a portable, automated analyzer that measures blood oxygen, carbon dioxide, pH, sodium, potassium, chloride, ionized calcium, and hematocrit in whole blood. The SenDx 100™ system is intended for use by trained technologists, nurses, physicians, and therapists. It can be used in laboratory, near patient or point-of-care settings.

510(k) Number (if known): _____

Device Name: SenDx 100™ pH, Blood Gas and Electrolyte Analysis System

Indications for Use:

The SenDx 100™ pH, Blood Gas and Electrolyte Analysis System (SenDx 100™) is intended to measure blood oxygen, carbon dioxide, pH, sodium, potassium, chloride, ionized calcium and hematocrit in whole blood.

The SenDx 100™ system can be used in the laboratory, near patient, or in point-of-care settings. It is intended for the measurement of blood gases, electrolytes and hematocrit in arterial or venous whole blood samples.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)

14-008

Technological Characteristics

As described in a previous 510(k) (K922631/B) for StatPal II, the StatPal II and the Mallinckrodt® GEM®-STAT are primarily intended for determination of arterial pH, pO_2 , and pCO_2 . Similarly, as described in the previous 510(k) (K954482) for the SenDx 100™, this device intended to be used for determination of arterial or venous pH, pCO_2 , pO_2 , Na^+ , K^+ , ionized Ca^{++} and hematocrit in whole blood. The present 510(k) submission adds chloride to the electrolyte panel of the SenDx 100™. The SenDx 100 is similar to the Mallinckrodt® GEM®-PREMIER, Corning 850 & 865, and NOVA STAT Profile 5 in intended use, methods of application and principles of operation.

The methods of application involve trained medical personnel in a central lab, stat lab or critical care environment. The StatPal II, SenDx 100 and GEM®-PREMIER can also be used near the patient due to the portable nature of the devices. In each of these devices, the principles of operation are similar or the same:

- polarographic (amperometric) pO_2 measurement
- potentiometric measurement pH, Na^+ , K^+ , Cl^- , iCa^{++} , and pCO_2 measurement
- conductance Hematocrit measurement

The SenDx 100 poses the same type of questions about safety and effectiveness of the equivalent devices.

NON-CLINICAL TESTING

Performance data was generated on-site at SenDx Medical, Inc. Comparisons were done with the following reference instruments:

- Corning 850 and spun hematocrit (micro centrifuge)

Linearity of Recovery:

- SenDx Medical, Inc.

Linearity of recovery for $p\text{CO}_2$ and $p\text{O}_2$ was assessed versus target recovery values employing blood tonometry. Linearity of recovery for pH, K^+ , Na^+ , Cl^- and iCa^{++} was assessed by selecting from the pooled whole blood data from five ranges evenly spread throughout the total range of measurement. Each range consisted of approximately 50 - 100 blood samples. The values for these ranges were independently verified against a Corning 850 Blood Gas and Electrolyte Analyzer. The resulting data were analyzed using full linear regression analysis. Regression slope, intercept, and correlation coefficient are reported.

Analyte	n	Slope	r	Intercept	Std Error Sy.x
pH	333	1.21	0.99	-1.56	0.017
$p\text{CO}_2$	384	1.00	0.99	0.92	1.83
$p\text{O}_2$	321	1.01	1.00	0.51	3.0
Na^+	465	1.09	0.99	-11.17	2.15
K^+	475	1.06	1.00	-0.18	0.13
Cl^-	414	1.03	0.99	1.10	1.66
iCa^{++}	600	1.01	1.00	-0.04	0.04
Hct	747	1.12	0.98	-2.42	1.69

Correlations:

- SenDx Medical, Inc.

The study was performed at SenDx Medical, Inc. comparing the SenDx 100™ to a Corning 850 Blood Gas and Electrolyte Analyzer and a spun hematocrit (micro-centerfuge).

Tonometered and spiked whole blood were tested in order to verify the accuracy of the SenDx 100™ system.

Analyte	n	Slope	r	Intercept	Std Error Sy.x
pH	472	1.23	0.99	-1.65	0.013
pCO ₂	413	1.00	0.99	0.49	1.62
pO ₂	1677	0.97	0.99	3.81	5.56
Na ⁺	619	1.17	0.99	-24.22	2.11
K ⁺	601	1.02	1.00	0.07	0.14
Cl ⁻	619	1.01	0.99	-0.10	1.54
iCa ⁺⁺	621	1.33	0.99	-0.4	0.05
Hct	1229	1.12	0.95	-4.63	2.07

Precision

- SenDx Medical, Inc.

An in-house precision study using quality control materials was performed over a period of 15 days. This study utilized multiple lots of sensor cassettes and calibration packs.

RNA Medical Qualidata levels 1, 2, 3 were used for blood gases and electrolytes, and RNA Medical hematocrit levels low and high were used for hematocrit. Each level was run in duplicate twice a day.

SenDx 100™		Mean	S. D.	%CV		Mean	S. D.	%CV
	pH				pCO₂			
Level 1		7.177	0.006	0.089	(mmHg)	67.5	2.1	3.1
Level 2		7.416	0.003	0.047		45.0	0.7	1.7
Level 3		7.612	0.006	0.073		24.7	0.7	2.8
	pO₂				Na⁺			
Level 1	(mmHg)	71.4	3.0	4.3	(mmol/L)	107.6	0.7	0.6
Level 2		109.5	2.0	1.9		130.1	0.5	0.4
Level 3		146.0	1.5	1.0		157.4	0.6	0.4
	K⁺				iCa⁺⁺			
Level 1	(mmol/L)	1.85	0.02	1.30	(mmol/L)	1.55	0.02	1.32
Level 2		4.39	0.03	0.78		1.19	0.01	0.97
Level 3		6.46	0.06	0.92		0.54	0.01	2.03
	Hct				Cl⁻			
Low	(%)	35.0	0.3	0.7	(mmol/L)			
High		58.2	0.5	0.8	Level 1	74.0	1.1	1.5
					Level 2	94.0	0.5	0.6
					Level 3	127.0	1.0	0.8

CLINICAL TESTING

Clinical studies were conducted of the SenDx 100™ system at four different geographical sites. This study involved four different SenDx 100™ analyzers, and multiple lots of sensor cassettes and calibrant solution packs. These clinical studies included split sample testing of over 50 samples per site and precision testing with QC control samples.

- **Hospital Stat Lab**

Clinical studies comparing the SenDx 100 system to the Corning 865, Nova Stat Profile 5, Corning Co-oximeter and spun hematocrit (micro centrifuge) methodologies have been conducted by evaluating over 400 split-samples at four clinical sites. Shown below is the performance of a representative site:

Reference Device: Corning 865 and CO-oximeter module

Analyte	n	Slope	r	Intercept	Std Error Sy.x
pH	120	0.89	0.99	0.841	0.013
pCO ₂	114	0.84	0.99	5.93	1.03
pO ₂	119	1.02	1.00	-0.08	5.77
Na ⁺	120	0.98	0.89	3.04	2.48
K ⁺	120	1.01	0.99	-0.15	0.07
iCa ⁺⁺	118	0.85	0.94	0.17	0.03
Hct	102	1.11	0.93	-4.03	2.55

- **Hospital Operating Room Point-Of-Care**

The SenDx 100™ system was subjected to operating room point-of-care use and at two different hospitals, operated by typical OR personnel. Shown below is the performance of a representative site:

Reference Device: Mallinckrodt Gem-Premier

Analyte	n	Slope	r	Intercept	Std Error Sy.x
pH	112	0.78	0.99	1.66	0.01
pCO ₂	106	0.80	0.96	4.96	1.56
pO ₂	108	0.79	0.95	54	28.5
Na ⁺	112	0.85	0.90	17.1	1.98
K ⁺	112	1.06	0.98	-0.4	0.20
iCa ⁺⁺	97	0.88	0.95	0.12	0.06
Hct	111	1.03	0.99	-2.35	1.85

• **Hospital Stat Lab**

Precision studies of the SenDx 100™ were conducted at four clinical sites over a five-day period. Reference quality control materials for pH, blood gases, electrolytes and hematocrit were tested. Each level was run in duplicate twice a day. Shown below are summarized precision data collected from these clinical sites:

Reference Device: Corning 865 and Co-oximeter Module

SUMMARY OF PRECISION STUDY

	<u>Level 1</u>			<u>Level 2</u>			<u>Level 3</u>		
	Mean	S. D.	% CV	Mean	S. D.	% CV	Mean	S. D.	% CV
pH									
Within Run	7.188	0.001	0.020	7.416	0.007	0.010	7.599	0.002	0.028
Within Day	7.188	0.001	0.013	7.416	0.001	0.017	7.601	0.003	0.035
Day to Day	7.193	0.003	0.046	7.423	0.004	0.059	7.607	0.005	0.072
Site to Site*	7.192	0.007	0.100	7.422	0.008	0.102	7.602	0.006	0.075
pCO₂									
Within Run	67.7	0.354	0.523	46.8	0.000	0.000	24.1	0.354	1.470
Within Day	67.9	0.374	0.551	47.0	0.238	0.507	23.9	0.263	1.099
Day to Day	67.6	0.642	0.952	46.0	1.015	2.216	23.9	0.760	3.332
Site to Site*	66.4	1.883	2.835	44.5	1.098	2.470	23.3	0.385	1.653
pO₂									
Within Run	68.5	0.636	0.930	106.8	1.061	0.994	144.5	0.071	0.049
Within Day	68.2	1.049	1.538	106.5	0.707	0.664	144.4	0.419	0.290
Day to Day	68.0	1.433	1.937	106.2	0.953	0.877	143.6	0.789	0.543
Site to Site*	68.2	2.502	3.667	107.4	1.328	1.236	143.1	2.546	1.779
Na⁺									
Within Run	108.1	0.141	0.131	129.8	0.071	0.054	157.4	0.424	0.270
Within Day	108.0	0.263	0.244	129.8	0.141	0.109	157.1	0.432	0.275
Day to Day	108.0	0.455	0.421	129.7	0.234	0.180	156.5	0.454	0.290
Site to Site*	107.4	2.133	1.987	129.2	1.452	1.124	156.2	1.176	0.753
K⁺									
Within Run	1.80	0.028	1.571	4.37	0.028	0.647	6.50	0.007	0.109
Within Day	1.80	0.017	0.950	4.38	0.030	0.681	6.48	0.021	0.318
Day to Day	1.81	0.013	0.716	4.37	0.015	0.347	6.46	0.031	0.477
Site to Site*	1.81	0.019	1.055	4.35	0.036	0.822	6.43	0.047	0.728
iCa⁺⁺									
Within Run	1.56	0.042	2.720	1.17	0.000	0.000	0.49	0.000	0.000
Within Day	1.55	0.029	1.856	1.16	0.015	1.290	0.50	0.006	1.166
Day to Day	1.55	0.019	1.236	1.16	0.009	0.763	0.50	0.004	0.714
Site to Site*	1.52	0.045	2.959	1.15	0.021	1.841	0.49	0.008	1.681
Hct									
Within Run	35.4	0.212	0.600	58.7	0.071	0.121			
Within Day	35.4	0.173	0.490	58.7	0.141	0.241			
Day to Day	34.8	0.425	1.220	57.8	0.722	1.249			
Site to Site*	34.2	0.546	1.594	57.3	0.797	1.391			

* For three clinical sites.

CONCLUSION FROM NONCLINICAL AND CLINICAL TESTING

From the nonclinical data we conclude that the performance of the SenDx 100™ system is equivalent to that of the Mallinckrodt GEM-PREMIER, Corning 865 and spun hematocrit for measurement of pH, pO_2 , pCO_2 , Na^+ , K^+ , Cl^- , iCa^{++} and hematocrit.

From the clinical study data we conclude that the performance of the SenDx 100™ system is substantially equivalent to that of the predicate devices routinely employed at the clinical sites, for measurement of pH, pO_2 , pCO_2 , Na^+ , K^+ , iCa^{++} and hematocrit. From these nonclinical and clinical studies we conclude that the performance of the SenDx 100™ system is substantially equivalent to that of the predicate devices routinely employed at several clinical sites.

These data adequately show that the SenDx 100™ system is safe and effective for its intended use in the laboratory or point-of-care. The data shows the SenDx 100™ system can be used at clinical sites for equivalent performance to the predicate devices routinely in use.

R. Chan

Signature of applicant

Sept. 29, 1997

Date



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 3 1997

Ruben Chairez, Ph.D.
Vice President, Regulatory Affairs/Quality Assurance
SenDx Medical, Inc.
1945 Palomar Oaks Way
Carlsbad, California 92009

Re: K973742
SenDx 100 pH, Blood Gas and Electrolyte Analysis System
Regulatory Class: II
Product Code: CHL, CGZ, CEM, JFP, JGS, GKF
Dated: September 23, 1997
Received: October 1, 1997

Dear Dr. Chairez:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

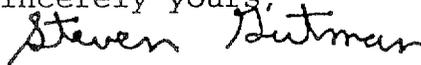
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) PRE-MARKET NOTIFICATION
SenDx 100 pH, BLOOD GAS AND ELECTROLYTE ANALYSIS SYSTEM

510(k) Number (if known): K973742

Device Name: SenDx 100™ pH, Blood Gas and Electrolyte Analysis System

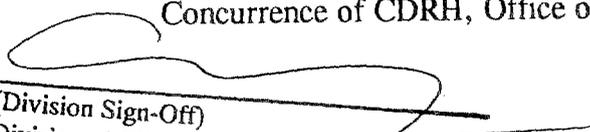
Indications for Use:

The SenDx 100™ pH, Blood Gas and Electrolyte Analysis System (SenDx 100™) is intended to measure blood oxygen, carbon dioxide, pH, sodium, potassium, chloride, ionized calcium and hematocrit in whole blood.

The SenDx 100™ system can be used in the laboratory, near patient, or in point-of-care settings. It is intended for the measurement of blood gases, electrolytes and hematocrit in arterial or venous whole blood samples.

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IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K973742

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)

15-002