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“510(K) SUMMARY”

(Sec. 807.92 Content and format of a 510(k) summary)

SECTION 807.92 a(1)

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SECTION 807.92 a(2)

DEVICE NAME: REDOX

TRADE NAME: Undetermined

COMMON NAME: Pneumatic Compression Device

CLASSIFICATION NAME: Compressible Limb Sleeve

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**PREDICATE DEVICE
CLAIMING EQUIVALENCE
TO:** COWBOY X

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DEVICE DESCRIPTION:

(Please note the controller device is the same controller used for the predicate device.)

The following device description is per section 3 of the draft "REVIEWER GUIDANCE FOR PREMARKET NOTIFICATION SUBMISSIONS," dated November, 1993, from the Anesthesiology and Respiratory Devices Branch and the Division of Cardiovascular, Respiratory, and Neurological Devices

The REDOX **functions** as an **intermittent pneumatic compression device** that aids in the circulation of blood in patients with lymphedema due to mastectomy, surgery, injury or disease. The REDOX is **not a life-supporting or life-sustaining device**. Also, the REDOX is **not an implant** (short-term or long-term), **nor** is it a **sterile device**. The REDOX is an **electrically-operated** (see electrical testing in test section), **software-driven** (see software testing in test section), **prescription device** (see drawing A-205360 in labeling section), which is used in a **hospital environment** (see mechanical testing in test section). The REDOX is comprised of two major components -- the **reusable** pump unit (controller device) (see drawings C-205303, D-205306, D-212032, D-235308 in engineering drawings section) and a **single-patient use** inflatable wrap (see drawings D-410009, D-410008, in engineering drawings section). **Neither component contains a drug nor biological product as a subcomponent.**

The REDOX unit uses a 16' hospital grade power cord (see drawing B-205337 in engineering drawings section) to supply a voltage of 115 VAC at a frequency of 60Hz with a maximum current consumption of 0.33 amperes and a maximum electrical leakage of less than 100 microamps (see electrical testing in test section) from its **power source**. An exterior shell made of **ABS material**, measuring 12" long by 10 3/4" wide by 7" deep, protects the subcomponents of the REDOX **11 pound** unit (see drawings D-205306, D-212032 in engineering drawings section).

The compressor inflates one or more of the wraps in minimum intervals of 10 seconds at a maximum pressure of not more than 180 mmHg (± 15 mmHg).

The unit **features** a microprocessor (see drawing D-210528 in engineering drawings section) that controls the unit's operation. The user selects: 1) the pressure from 140 to 180 mmHg, in 10 mmHg increments; 2) the cycle time from 20 to 60 seconds, in 10 second increments, and; 3) the hold time from 1 to 5 seconds, in 1 second increments (see software testing in test section). Selections are made by the user interfacing with the membrane switch located on the front of the unit (see drawing C-205315 in engineering drawings section and drawing B-235309 in labeling section). The microprocessor also has **detection capabilities** to monitor the pressure in the wrap(s), adjusting the in and out flow of air on every cycle, to ensure that the target pressure is consistently maintained. If

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for any reason the target pressure cannot be maintained, the microprocessor **alarm capabilities** will activate both visual and audio alarms (see software testing in test section). These **alarm capabilities** are built in to detect high pressure, low pressure and/or unit malfunction situations, should they ever occur (see software testing in test section).

The **non-sterile** inflatable wraps are for **single patient use only** (see labeling section). Arm wraps (see drawings D-410009, D-410008, in engineering drawings section) are designed to fit around and compress the veins in the arm, including both collateral veins and deep veins. Hook-and-loop fasteners are used to hold the wrap comfortably around the arm. The wraps are RF-welded to create an air chamber that can then be inflated by the REDOX unit. This air chamber is what actually applies pressure against the body.

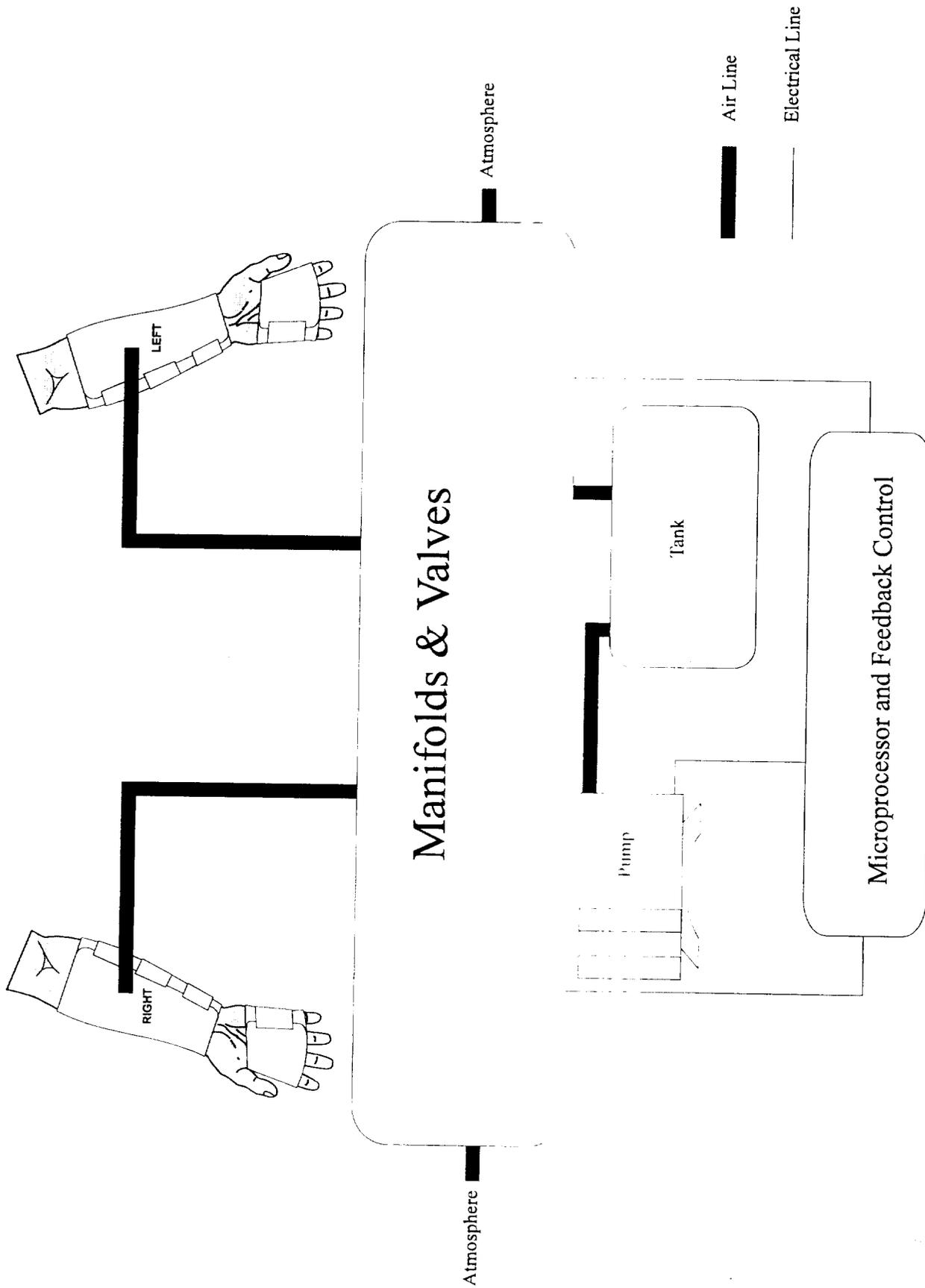


Figure A.1

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INTENDED USE:

MEDICAL INDICATIONS:

The REDOX pump is indicated for patients who would benefit from a pneumatic compression device applied to the arm. Such benefits include helping to:

- Prevent Deep Venous Thrombosis (DVT)
- Prevent venous stasis in the upper extremities.
- Enhance arterial circulation in the upper extremities.
- Reduce post-operative pain and swelling in the upper extremities.
- Reduce edema in the upper extremities.
- Reduce wound healing time in the upper extremities
- Treat and assist healing of cutaneous ulceration in the upper extremities.
- Reduce compartmental pressures in the upper extremities.
- Reduce the need for anticoagulant medications prescribed for the prevention of DVT.

MEDICAL CONTRAINDICATIONS:

Patient conditions for which the REDOX pump is contraindicated include:

- Presumptive evidence of congestive heart failure.
- Suspected pre-existing DVT.

DIFFERENCES IN INDICATIONS:

The indications for the REDOX are the same as those for the predicate device. The only difference being application to the upper extremity versus the lower extremity.

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TECHNOLOGICAL CHARACTERISTICS:

	PREDICATE DEVICE: COWBOY X	SUBMITTED DEVICE: REDOX
MAIN UNIT:		
Structural Design	Portable	Same
Material	ABS, Aluminum	Same
Internal Components	Pump, Tank, Solenoid Valves	Same
Power Supply	115 VAC 60Hz .33 Amp.	Same
Electronics	Microprocessor	Same
Software	"C" Language Program	Same
OPERATION:		
Cycle Time	20-60 sec. (10 sec. increments)	Same
Hold Time	1-5 sec. (1 sec. increments)	Same
Pressure Settings	140-180 mmHg (10 mmHg increments)	Same
Pressure Readings	±15 mmHg	Same
User Interface	Yes	Yes
ACCESSORIES:		
Foot Wrap	Yes	No
Arm Wrap	No	Yes
Material	Lycra Interior Loop Exterior	Same
Manufacturing Process	Die Cutting R-F Welding Sewing Hot Stamping	Same
Tooling	"T" Shaped	"C" Shaped

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DISCUSSION OF NONCLINICAL TESTING:

SOFTWARE TEST PROTOCOL AND PROCEDURES

The test protocol for the REDOX is very simple. The REDOX software will pass if it can operate within specifications. These specifications include being able to maintain an average pressure in the inflatable wrap(s) within ± 15 mmHg of target pressure throughout the entire hold time and setting off visual and audio alarms in the event of a high pressure, low pressure, and/or unit malfunction. If for any reason any one of these specifications are not met, the software is rejected.

The software test procedures for the REDOX have been designed to take advantage of our experience with the predicate device. First, we will focus on pulsation settings that will give the system the least amount of time to recover. Second, we will focus on low pressure, high pressure, and unit malfunction **alarms**. Finally, we will focus on **stressing** the software with rapid input and operational disruptions.

PULSATION VERIFICATION PROCEDURES

1. Right Foot Wrap
 - 1.1 Test pressure at the wrap per operation and maintenance manual page 6-2
 - 1.2 Wrap foot wrap around a simulated foot model
 - 1.3 Set pulsation settings at pressure setting 1, cycle time at 20, and hold time at 1
 - 1.4 From the FOR SERVICE USE ONLY screen press VIEW then press HOME
 - 1.5 Under RS write down the pressure reading shown on the screen for five consecutive cycles after the unit has "Ramped-up"
 - 1.6 Repeat process for:
 - 1.6.1 Pressure setting at 1, cycle time at 20, and hold time at 2
 - 1.6.2 Pressure setting at 1, cycle time at 20, and hold time at 3
 - 1.6.3 Pressure setting at 1, cycle time at 20, and hold time at 4
 - 1.6.4 Pressure setting at 1, cycle time at 20, and hold time at 5
 - 1.6.5 Pressure setting at 3, cycle time at 20, and hold time at 1
 - 1.6.6 Pressure setting at 3, cycle time at 20, and hold time at 2
 - 1.6.7 Pressure setting at 3, cycle time at 20, and hold time at 3
 - 1.6.8 Pressure setting at 3, cycle time at 20, and hold time at 4
 - 1.6.9 Pressure setting at 3, cycle time at 20, and hold time at 5
 - 1.6.10 Pressure setting at 5, cycle time at 20, and hold time at 1
 - 1.6.11 Pressure setting at 5, cycle time at 20, and hold time at 2

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1.6.12 Pressure setting at 5, cycle time at 20, and hold time at 3

1.6.13 Pressure setting at 5, cycle time at 20, and hold time at 4

1.6.14 Pressure setting at 5, cycle time at 20, and hold time at 5

2. Left Foot Wrap

- 2.1 Test pressure at the wrap per operation and maintenance manual page 6-2
- 2.2 Wrap foot wrap around a simulated foot model
- 2.3 Set pulsation settings at pressure setting 1, cycle time at 20, and hold time at 1
- 2.4 From the FOR SERVICE USE ONLY screen press VIEW then press HOME
- 2.5 Under LS write down the pressure reading shown on the screen for five consecutive cycles after the unit has "Ramped-up"
- 2.6 Repeat process for same pulsation settings described in steps 1.6.1 thru 1.6.14

3. Left & Right Foot Wrap

- 3.1 Test pressure at the wrap per operation and maintenance manual page 6-2
- 3.2 Wrap foot wraps around simulated foot models
- 3.3 Set pulsation settings at pressure setting 1, cycle time at 20, and hold time at 1
- 3.4 From the FOR SERVICE USE ONLY screen press VIEW then press HOME
- 3.5 Under RS and LS write down the pressure reading shown on the screen for five consecutive cycles after the unit has "Ramped-up"
- 3.6 Repeat process for same pulsation settings described in steps 1.6.1 thru 1.6.14

4. Right Arm Wrap

- 4.1 Test pressure at the wrap per operation and maintenance manual page 6-2
- 4.2 Wrap arm wrap around a simulated arm model
- 4.3 Set pulsation settings at pressure setting 1, cycle time at 20, and hold time at 1
- 4.4 From the FOR SERVICE USE ONLY screen press VIEW then press HOME
- 4.5 Under RS write down the pressure reading shown on the screen for five consecutive cycles after the unit has "Ramped-up"
- 4.6 Repeat process for same pulsation settings described in steps 1.6.1 thru 1.6.14

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5. Left Arm Wrap

- 5.1 Test pressure at the wrap per operation and maintenance manual page 6-2
- 5.2 Wrap arm wrap around a simulated arm model
- 5.3 Set pulsation settings at pressure setting 1, cycle time at 20, and hold time at 1
- 5.4 From the FOR SERVICE USE ONLY screen press VIEW then press HOME
- 5.5 Under LS write down the pressure reading shown on the screen for five consecutive cycles after the unit has "Ramped-up"
- 5.6 Repeat process for same pulsation settings described in steps 1.6.1 thru 1.6.14

6. Left & Right Arm Wrap

- 6.1 Test pressure at the wrap per operation and maintenance manual page 6-2
- 6.2 Wrap arm wraps around simulated arm models
- 6.3 Set pulsation settings at pressure setting 1, cycle time at 20, and hold time at 1
- 6.4 From the FOR SERVICE USE ONLY screen press VIEW then press HOME
- 6.5 Under RS and LS write down the pressure reading shown on the screen for five consecutive cycles after the unit has "Ramped-up"
- 6.6 Repeat process for same pulsation settings described in steps 1.6.1 thru 1.6.14

ALARM TESTING PROCEDURE

1. Low pressure alarm right foot wrap
 - 1.1 With scissors cut a 1/8" slit in the bladder area of the wrap
 - 1.2 With a good inflatable wrap allow the unit to "ramp-up" at pressure setting 1, cycle time 20, and hold time 1
 - 1.3 Replace the good inflatable wrap with the inflatable wrap in step 1.1
 - 1.4 If after 5 consecutive cycles the unit alarms then the software passes. Otherwise the software fails
2. Low pressure alarm left foot wrap repeat steps 1.1 thru 1.5
3. Low pressure alarm right arm wrap repeat steps 1.1 thru 1.5
4. Low pressure alarm left arm wrap repeat steps 1.1 thru 1.5

5. High pressure alarm right foot wrap
 - 5.1 Kink PVC hose from the unit to the inflatable wrap
 - 5.2 If after 5 consecutive cycles the unit alarms then the software passes. Otherwise the software fails
 - 5.3 Repeat steps 6.1 and 6.2 for all possible inflatable wrap combinations

6. Unit malfunction
 - 6.1 Disconnect PVC hose from unit
 - 6.2 If the unit alarms then the software passes. Otherwise the software fails

SOFTWARE STRESS TEST:

1. Rapid input
 - 1.1 Select any pulsation setting
 - 1.2 Allow the unit to “ramp-up”
 - 1.3 Now rapidly change pulsation setting. If the unit adjusts to the new pulsation setting then the software passes. Otherwise the software fails
 - 1.4 Repeat steps 1.1 thru 1.3 for right and left foot and arm wraps

2. Operational disrupt
 - 2.1 Select any pulsation setting
 - 2.2 Allow the unit to “ramp-up”
 - 2.3 Now while a wrap is inflated, change the pulsation setting. If on the next cycle the unit operates at the new pulsation setting the software passes. Otherwise the software fails
 - 2.4 Repeat steps 2.1 thru 2.3 for right and left foot and arm wraps

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RESULTS OF NONCLINICAL TESTING:

REDOX and Predicate Device (K944567) Software Testing

Test Unit: 61578 Performed by T. Randolph Date: 8/2/95

Accessories Wrapped Around High Density Foam

Pressure Settings (PS)(1=140 mmHg, 3=160mmHg, 5=180mmHg)

Cycle Time (CT) (sec.) Hold Time (HT) (sec.)

	FOOT WRAP				ARM WRAP			
	RIGHT	LEFT	BILATERAL RIGHT LEFT		RIGHT	LEFT	BILATERAL RIGHT LEFT	
PS 1, CT 20, HT 1	144	132	144	144	152	152	148	136
	140	132	144	140	152	144	144	144
	144	132	140	140	152	136	148	144
	144	132	140	140	152	140	140	144
	144	128	140	140	152	140	144	136
AVERAGE	143.2	131.2	141.6	140.8	152	142.4	144.8	140.8

PS 1, CT 20, HT 2	148	124	144	140	152	144	148	140
	148	136	144	140	156	144	156	140
	148	132	144	132	156	148	148	140
	148	132	152	140	156	148	148	144
	144	132	144	140	152	148	148	144
AVERAGE	147.2	131.2	145.6	138.4	154.4	146.4	149.6	141.6

PS 1, CT 20, HT 3	144	132	148	132	156	152	148	144
	140	132	144	140	148	140	148	144
	144	132	144	144	148	144	148	144
	144	132	144	132	148	140	148	152
	148	132	144	144	148	144	152	144
AVERAGE	144	132	144.8	138.4	149.6	144	148.8	145.6

PS 1, CT 20, HT 4	140	140	148	144	148	140	144	140
	144	128	148	144	156	140	140	144
	148	124	148	144	152	140	152	140
	148	128	144	144	156	140	148	148
	152	144	144	144	148	140	148	148
AVERAGE	146.4	132.8	146.4	144	152	140	146.4	144

PS 1, CT 20, HT 5	144	144	144	144	148	152	148	140
	144	144	144	144	152	152	152	144
	152	128	144	144	144	140	144	140
	148	128	148	144	156	140	148	148
	152	128	148	136	148	152	148	148
AVERAGE	148	134.4	145.6	142.4	149.6	147.2	148	144

	FOOT WRAP				ARM WRAP			
	RIGHT	LEFT	BILATERAL RIGHT LEFT		RIGHT	LEFT	BILATERAL RIGHT LEFT	
PS 3, CT 20, HT 1	163	152	163	167	163	167	171	163
	156	148	156	156	171	167	171	163
	163	156	156	159	171	171	171	163
	159	148	148	159	167	167	167	159
	159	144	163	159	167	156	171	167
AVERAGE	160	149.6	157.2	160	167.8	163.6	170.2	163

PS 3, CT 20, HT 2	167	152	159	159	175	167	167	163
	167	152	163	163	171	167	163	167
	167	152	159	163	171	167	167	167
	167	152	163	163	171	167	171	167
	167	152	159	163	171	159	167	171
AVERAGE	167	152	160.6	162.2	171.8	163.4	167	167

PS 3, CT 20, HT 3	167	152	167	171	171	171	163	167
	167	148	171	163	167	163	163	163
	171	148	163	163	167	167	167	167
	167	152	159	163	167	171	163	167
	167	152	163	163	167	171	171	163
AVERAGE	167.8	150.4	164.6	164.6	167.8	168.6	163.4	165.4

PS 3, CT 20, HT 4	167	152	159	163	167	171	163	167
	171	152	163	163	171	171	171	152
	171	152	163	163	167	171	167	167
	167	152	163	163	167	163	171	152
	171	152	163	163	167	163	167	159
AVERAGE	169.4	152	162.2	163	167.8	167.8	167.8	159.4

PS 3, CT 20, HT 5	163	156	159	167	167	163	167	163
	167	152	163	163	167	163	171	163
	167	152	163	163	167	167	171	163
	171	152	163	163	171	171	156	152
	163	152	163	163	167	156	156	148
AVERAGE	166.2	152.8	162.2	163.8	167.8	164	164.2	157.8

	FOOT WRAP				ARM WRAP			
	RIGHT	LEFT	BILATERAL RIGHT LEFT		RIGHT	LEFT	BILATERAL RIGHT LEFT	
PS 5, CT 20, HT 1	187	179	187	175	191	183	179	183
	187	183	179	175	187	175	187	179
	187	183	183	175	191	187	179	187
	179	183	179	175	187	187	187	183
	187	187	179	167	187	183	179	179
AVERAGE	185.4	183	181.4	173.4	188.6	183	182.2	182.2

PS 5, CT 20, HT 2	191	191	183	175	187	191	191	179
	191	187	191	179	187	183	175	179
	191	183	183	179	191	191	187	179
	191	183	187	179	187	183	191	187
	191	179	183	179	187	183	191	187
AVERAGE	191	184.6	185.4	178.2	187.8	186.2	187	182.2

PS 5, CT 20, HT 3	191	191	191	183	187	179	187	175
	191	191	183	167	187	183	191	179
	187	191	187	183	187	183	191	179
	191	179	183	183	187	183	191	179
	191	179	183	187	187	179	191	179
AVERAGE	190.2	186.2	185.4	180.6	187	181.4	190.2	178.2

PS 5, CT 20, HT 4	191	191	183	187	187	179	187	171
	191	179	183	187	187	183	187	175
	191	175	183	175	187	183	187	191
	191	167	187	179	187	183	187	171
	191	175	187	175	187	183	191	187
AVERAGE	191	177.4	184.6	180.6	187	182.2	187.8	179

PS 5, CT 20, HT 5	191	175	187	183	187	175	187	175
	187	187	187	175	187	179	187	191
	191	187	191	187	187	175	191	191
	187	183	183	179	187	183	179	191
	187	187	191	175	191	183	191	187
AVERAGE	188.6	183.8	187.8	179.8	187.8	179	187	187

ALARM TESTING:

	LOW PRESSURE		HIGH PRESSURE	
	YES	NO	YES	NO
FOOT WRAPS:				
Right Only	X		X	
Left Only	X		X	
Bilateral: Right	X		X	
Left	X		X	
ARM WRAPS:				
Right Only	X		X	
Left Only	X		X	
Bilateral: Right	X		X	
Left	X		X	
UNIT MALFUNCTION:				
Right Hose Removed	X		X	
Left Hose Removed	X		X	
Both Hoses Removed	X		X	

SOFTWARE STRESS TEST:

	RAPID INPUT		OPERATIONAL DISRUPT	
	PASS	FAIL;	PASS	FAIL
FOOT WRAPS:				
Right Only	X		X	
Left Only	X		X	
Bilateral: Right	X		X	
Left	X		X	
ARM WRAPS:				
Right Only	X		X	
Left Only	X		X	
Bilateral: Right	X		X	
Left	X		X	

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CONCLUSIONS:

The conclusion that follows is based on section 807.92 a(4) "DEVICE DESCRIPTION" pages 1-3, section 807.92 a(5) "INTENDED USE" pages 3-4, section 807.92 a(6) "TECHNOLOGICAL CHARACTERISTICS" pages 4-5, and section 807.92 b(1) "NONCLINICAL TEST AND RESULTS" pages 5-12 of the "510(K) SUMMARY".

The REDOX and the predicate device both employ the same reusable pump unit (controller), including the same electronics and software. The only difference in the REDOX and the predicate device is the inflatable wrap, which is intended for single patient use. The difference is limited to the general shape of the wrap and the location where the wrap is to be used. There has been no change in the function (squeezing the veins) of the wrap. The REDOX wrap simply squeezes the veins in the arm where the predicate wrap squeezes the veins in the foot.

The reusable pump unit of REDOX and the predicate device are the same. Therefore, the structural design, materials, internal components, power supply, electronics, and software are the same. Also, the operation of the unit is the same. This includes the cycle time, hold time, pressure settings, and user interface. The single patient use, inflatable wrap is different; however, the same material and manufacturing processes are used. Therefore, the technological characteristics of REDOX and the predicate device are the same.

Both the REDOX and the predicate device used the same reusable pump unit for the nonclinical testing. Using the same protocol and procedures, there was no statistical difference in the pulsation verification testing. Also, the alarm and software stress testing yielded identical results. Therefore, the nonclinical tests and results were the same.

The conclusions drawn from the nonclinical testing is that the device is safe, effective, and performs as well as the legally marketed predicate device.

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