MAR 2 1 2014 K131877

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Date Prepared:	18-Mar-14
AutoMedx, Inc. 1420 Lakeside Parkway, Suite 102 Flower Mound, Texas 75028	 Tel - 972-586-7500 Fax - 972-408-4177
Official Contact:	James Evans - President
Proprietary or Trade Name:	SAVe II™ SAVe II™ Basic
Common/Usual Name:	Powered emergency ventilator
Classification Name:	Powered emergency ventilator Procode – BTL CFR – 868.5925 Class 2
Predicate Devices:	Impact Instruments – Uni-Vent Model 754 – K931473 AutoMedx – SAVe™ - K071221

Device Description:
The SAVe II™ and SAVe II™ Basic ventilators are battery powered compressors to deliver automated, controlled positive pressure breaths with ambient air for up to 10 hours. It is designed to augment the capabilities of first responders by supplementing Bag Valve Mask (BVM) manual ventilation delivery with an automated solution that can be rapidly deployed by minimally skilled providers in environments where compressed oxygen is unavailable or ill-advised.

To support use in emergency situations, the SAVe II™ is portable and easy to carry. Rapid initial setup is enabled by default ventilator settings based on adult patient's height, ranging from 4'6" to 6'6" weighing at least 45 kg, organized in a circular-shaped graphic. To mitigate the risk of patient injury, airway pressure is monitored and users are alerted to potentially dangerous low and high pressure situations. Immediate patient injury due to high pressure is avoided by a pressure cut-off that triggers an exhalation if inspiratory pressure exceeds device settings. Rapid troubleshooting is enabled by visual alarm indicators located together at the bottom of the unit that identifies the most likely cause of the triggered alarm.

- SAVe II™
  - This is a full feature unit and the predicate is the Impact Uni-Vent Model 754 (K931473)
  - Note the some references have been made to Enhanced SAVe, which is the identical to the SAVe II™
- SAVe II™ Basic
  - This is similar to the SAVe II™ but has fewer options and features.
  - The predicate is the legacy product AutoMedx SAVe (K071221)

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Indications for Use:
The SAVe II™ series are intended to provide short-term ventilatory support to adults during CPR or when Positive-Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure (ARF). The SAVe II™ series are appropriate for adults that weigh at least 45 kg. It is intended to be used in pre-hospital, field hospitals, and transport environments.

Contraindications:

Contraindication	SAVe II™	SAVe II™ Basic
Should not be used on patients weighing less than 45 ***kilograms***	Yes	Yes
Should not be used in situations where Positive Pressure Ventilation (PPV) is contraindicated.	Yes	Yes
Do not use the device for extended periods without monitoring blood gases. As duration of use increases, the need for close monitoring of CO_2 and O_2 levels also increases. This is especially true for patients over 6' 9".	Yes	Yes
Spontaneously breathing patients may not synchronize with ventilator. If spontaneously breathing patient has difficulty synchronizing with the device, consider discontinuing use.	Yes	Yes
Do not set ***PEEP*** above zero (0) when performing ***CPR***.	Yes	N/A*

*The SAVe II™ Basic does not have an adjustable PEEP setting, thus is not applicable.

Technological Characteristics:
The principle of operation for both models is that they use a battery-powered compressor to deliver air to a patient for up to 10 hours on a single charge.

The device is software controlled to deliver ventilation to the patient based upon pre-set parameters, which are based upon height of the adult patient and for the SAVe II™ model may be adjusted by the user.

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We use a standard ventilator circuit to connect the SAVe II™ to the patient with the patient connection being face mask, supralaryngeal airway (laryngeal tube), endotracheal tube or tracheostomy tube.

Table 1 – Comparison of the 2 - SAVe II™ Models

	SAVe II™	SAVe II™ Basic
Indications for Use	The SAVe II™ series are intended to provide short-term ventilatory support to adults during CPR or when Positive-Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure (ARF). The SAVe II™ series are appropriate for adults that weigh at least 45 kg. It is intended to be used in pre-hospital, field hospitals, and transport environments.	The SAVe II™ series are intended to provide short-term ventilatory support to adults during CPR or when Positive-Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure (ARF). The SAVe II™ series are appropriate for adults that weigh at least 45 kg. It is intended to be used in pre-hospital, field hospitals, and transport environments.
User Population	Qualified and trained users	Qualified and trained users
Patient Population	Adults Patients weighing >45 kg	Adult Patients weighing >45 kg
Environment of Use	pre-hospital field hospitals transport	pre-hospital field hospitals transport
Breath Types / Ventilation Modes		
Breath Type	Volume-targeted Time-cycled Pressure limited	Volume-targeted Time-cycled Pressure limited
Main Ventilation Mode	Assist Control	Assist Control
Basic and Advanced User Modes	Yes	No
Manual Triggered Breath	Yes	Yes
CPR Mode	Yes	No
Air Source	Ambient / Oxygen	Ambient / Oxygen
Settings		
TV [mL/breath]	200 – 800 increments of 50	300 – 700 increments of 100
RR [br/min]	8 – 20	10 fixed
Inspiratory Flow [L/min]	Up to 27	Up to 27
I:E Ratio	Fixed at 1:3 or 1:2	Fixed at 1:3 or 1:2
PIP Limit [cmH2O]	10 – 60	30 fixed
PEEP [cmH2O]	Internal: 0 – 10	0 fixed
Supplemental Oxygen (FIO2)	21 - 100%	21 – 100%

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	SAVe II™	SAVe II™ Basic
Alarms/Indicators		
Start-up Self-Test	Yes	Yes
Circuit Disconnect	Yes	Yes
Over Pressure / Blockage	Yes	Yes
External Power Indicator	Yes	Yes
Low Battery	Yes	Yes
Detect Spontaneous Breath	Yes	Yes
Device Temperature Too High	Yes	Yes
Excessive PEEP ("Breath Stacking")	Yes	Yes
I:E Ratio Exceeded	Yes	No
Physical Characteristics		
Weight [lbs]	2.6	2.6
Size	6.5" x 6.25" x 2.0" (81 in3)	6.5" x 6.25" x 2.0" (81 in3)
Display/User Interface	Membrane Panel, LEDs, and 7-Segment Displays, Increment/Decrement Buttons	Membrane Panel, LEDs, and 7-Segment Displays
Interfaces With		
Patient Breathing Circuit	Active Breathing Valve	Active Breathing Valve
Oxygen	Low flow sources O_2 flow meters O_2 concentrators	Low flow sources O_2 flow meters O_2 concentrators
EtCO2 Detector	Yes (External)	Yes (External)
Power		
Battery	Rechargeable, Lithium Ion	Rechargeable, Lithium Ion
Duration per charge	10 hrs @TV=600,RR=10,PEEP=5	10 hrs @TV=600,RR=10,PEEP=0
External Power Supply	Input: 100 – 240 VAC / 50 – 60 Hz Output: 16.8 VDC	Input: 100 – 240 VAC / 50 – 60 Hz Output: 16.8 VDC

Substantial Equivalence Discussion – SAVe II™

Table 2 compares the SAVe II™ vs. the predicate Impact Model 754 (K931473). One will note that the predicate has more features than the proposed SAVe II™ and thus one could consider it a subset of the predicate.

It should be noted that our legacy SAVe™ ventilator (K071221) has many of the equivalent function and features of the SAVe II™. The legacy SAVe™ used the Impact Model 754 (K931473) as its predicate when it was reviewed and found substantially equivalent.

In addition, we have included in **Table 2** a reference predicate, the SAVe™ ventilator (K071221).

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Table 2 – Comparison of Proposed SAVe II™ and Predicate Impact Model 754 (K931473) and Reference – SAVe™ (K071221)

Features	SAVe II™	Impact Uni-Vent Model 754 K931473)	AutoMedx SAVe™ - K071221
Overview	Robust functionality in small form factor, completely self-contained, meant to be used by minimally trained providers.	Robust functionality in large form factor, completely self-contained, meant to be used by trained providers.	Robust functionality in small form factor, completely self-contained, meant to be used by minimally trained providers.
Indications for Use	The SAVe II™ series are intended to provide short-term ventilatory support to adults during CPR or when Positive-Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure (ARF). The SAVe II™ series are appropriate for adults that weigh at least 45 kg. It is intended to be used in pre-hospital, field hospitals, and transport environments.	Intended to provide ventilatory support to individuals during CPR or when Positive-Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure (ARF).	Intended to provide short-term ventilatory support to individuals during CPR or when Positive-Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure (ARF).
Users Population	Qualified and trained users	Qualified and trained users	Qualified and trained users
Patient Population	Adult Patients weighing >45 kg	Adult, Pediatric, Infants	Patients weighing >45 kg
Target Environment	pre-hospital field hospitals transport	pre-hospital field hospitals transport	pre-hospital field hospitals transport
Breath Types / Ventilation Modes			
Breath Type	Volume-targeted Time-cycled Pressure limited	Volume-targeted Time-cycled Pressure limited	Volume-targeted Time-cycled Pressure limited
Main Ventilation Mode	Assist Control	Assist Control	Assist Control
Basic and Advanced User Modes	Yes	Yes	No
Manual Triggered Breath	Yes	Yes	No
CPR Mode	Yes	Yes	No

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Features	SAVe II™	Impact Uni-Vent Model 754 K931473)	AutoMedx SAVe™ - K071221
Air Source	Ambient / Oxygen	Ambient / Oxygen	Ambient / Oxygen
Settings			
TV [mL/breath]	200 – 800 increments of 50	0 – 3000	600 (fixed)
RR [br/min]	8 – 20	1 to 150	10 (fixed)
Inspiratory Flow [L/min]	Up to 27	Up to 60	Up to 17
I:E Ratio	Fixed at 1:3 or 1:2	1:1 to 1:599	Fixed at 1:2
PIP Limit [cmH2O]	10 – 60	15 – 100	38
PEEP [cmH2O]	Internal: 0 – 10	0 – 20	0
Supplemental Oxygen (FIO2)	21 - 100%	21 – 100%	21 - 60%
Alarms/Indicators			
Startup Self-Test	Yes	Yes	Yes
Circuit Disconnect	Yes	Yes	Yes
Over Pressure / Blockage	Yes	Yes	Yes
External Power Indicator	Yes	Yes	Yes
Low Battery	Yes	Yes	Yes
Detect Spontaneous Breath	Yes	Yes	Yes
Device Temperature Too High	Yes	No	Yes
Excessive PEEP ("Breath Stacking")	Yes	Yes	Yes
I:E Ratio Exceeded	Yes	Yes	No
Technological and Physical Characteristics			
Source for ventilation	Internal, battery operated compressor	Internal, battery operated compressor	Internal, battery operated compressor
Weight [lbs]	2.6	13.0	3.1
Display/User Interface	Membrane Panel, LEDs, and 7-Segment Displays, Increment/Decrement Buttons	Rotary Switches, LEDs, Graphic Display	Rotary Switch, LEDs
Interfaces With			
Patient Breathing Circuit	Active Breathing Valve	Active Breathing Valve	Passive Breathing Valve
Oxygen	Low flow sources, O2 flow meters, and O2 concentrators	Low & High flow sources, O2 flow meters, and O2 concentrators	Low flow source, O2 flow meter, and O2 concentrator (up to 10 L/min)
EtCO2 Detector	Yes (External)	Yes (External)	Yes (External)

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Features	SAVe II™	Impact Uni-Vent Model 754 K931473)	AutoMedx SAVe™ - K071221
Power			
Battery	Rechargeable, Lithium Ion	Rechargeable, SLA	Rechargeable, SLA
Duration per charge	10 hrs @TV=600,RR=10,PEEP=5	3 hrs using internal pump 12 hours using external gas	5.5 hrs @TV=600,RR=10,PEEP=0
External Power Supply	Input: 100 – 240 VAC / 50 – 60 Hz Output: 16.8 VDC	Input: 90 – 265 VAC / 47 – 400 Hz Output: 12 VDC	Input: 100 – 240 VAC / 47 – 63 Hz Output: 15 VDC

Discussion of Substantial Equivalence and Any Differences

The SAVe II™ is viewed as substantially equivalent to the predicate, Impact Model 754 (K931473) device because:

Indications –
The proposed indications for use which are to provide short-term ventilatory support to adults during CPR or when Positive-Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure (ARF) is identical to the predicate Impact Model 754 (K931473)
Discussion - While the predicate Impact has more features and functions the SAVe II™ is a smaller, lighter weight portable ventilator design more specifically for the intended use of a portable emergency ventilator, while the predicate Impact has a broader range of uses, one of which is as a portable emergency ventilator.

Environment of Use –
The proposed environments of use as a transport ventilator that can be used in field hospitals, pre-hospital and transport settings which are identical to the predicate Impact Model 754 (K931473) and the reference predicate AutoMedx SAVe™ (K071221).
Discussion – The environments for use are identical and thus substantially equivalent.

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Patient Population –
The SAVe II™ is intended for adult patients greater than 45 kg.
Discussion – The predicate Impact Model 754 (K931473) is used for pediatrics to adult and the reference predicate AutoMedx SAVe™ (K071221) for patients greater than 45 kg, the proposed SAVe II™ is within the patient population of the predicates and thus can be considered substantially equivalent.

Technology –

Principle of Operation –
The Save II™ is a battery powered ventilator with an internal compressor which generates the positive pressure to be delivered. It primary gas source is ambient air but supplemental oxygen may be used. It is has integrated software and electronics which control the functions and alarms. The user interface is a membrane panel with LEDs. The patient interface is a standard ventilator circuit that can connect to the patient via a face mask, supraglottic airway, endotracheal tube, or tracheostomy tube.
Discussion – The SAVe II™ and the predicate Impact Model 754 (K931473) as well as the reference predicate AutoMedx SAVe™ (K071221) have the identical operating and technological characteristics and modes of operation. The User Interface of the SAVe II™ is a membrane panel vs. rotary switches for the predicate, which is easier to use and does not pose any new safety concerns.

Alarms –
The SAVe II™ has full complement of alarms expected for a ventilator. These include – circuit disconnect, over pressure / blockage, external power indicator, low battery, detect spontaneous breathing Excessive PEEP, I:E Ratio limits, device temperature too high.
Discussion - The SAVe II™ and the predicate have the same set of alarms, except the SAVe II™ has a device high temperature alarm which for the proposed environment of use is a safety feature.

Materials –
The materials in the gas pathway are identical to the reference predicates, AutoMedx SAVe™ and Impact Model 754, and / or have been tested per VOC and $PM_{2.5}$.

G95-1 and ISO 10993 would suggest the level of patient contact as:

- External Communicating (indirect gas pathway)
- Tissue contact
- Limited duration (< 24 hours)

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Non-clinical Testing –

Bench Testing –
We have performed a complete set of performance testing to the device specifications and confirmed that the device meets it performance requirements. We also performed comparative bench testing to the predicate.

In addition, we performed durability testing up to 2,000 hours, EMC, EMI, electrical safety, mechanical and environmental testing and Atmospheric Pressure Testing at both 10.15 psia (700 hPa) and 15.95 psia (1100 hPa). The latter represents a simulated altitude of 10,000 feet.

Discussion – We performed a full complement of bench tests that demonstrated that the SAVe II™ met its performance requirements and specifications. It can be considered substantially equivalent to the predicates having undergone similar or identical testing as the predicates.

Substantial Equivalence Conclusion –

The sponsor has demonstrated through performance testing, comparison of design and features, and non-clinical testing that the proposed device and predicate can be found to be substantially equivalent.

Substantial Equivalence Discussion – SAVe II™ - Basic

Table 3 compares the SAVe II™ Basic vs. the predicate AutoMedx SAVe™ (K071221).

Much of the testing that is presented in this submission has been performed on the SAVe II™ which has more functions and features than the SAVe II™ Basic; but the entire unit is identical. The only differences, as outlined in **Table 1** above, are that some features / functions are removed in the Basic model, making it closer in function to our predicate SAVe™ (K071211).

Discussion of Substantial Equivalence and Any Differences

The SAVe II™ Basic is viewed as substantially equivalent to the predicate AutoMedx SAVe™ (K071221) device because:

Indications –
The proposed indications for use which are to provide short-term ventilatory support to adults during CPR or when Positive-Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure (ARF) is identical to the predicate AutoMedx SAVe™ (K071221).
Discussion - The SAVe II™ Basic is identical to the predicate AutoMedx SAVe™ (K071221).

Environment of Use –
The proposed environments of use as a transport ventilator that can be used in field hospitals as well as pre-hospital and transport settings is identical to the predicate AutoMedx SAVe™ (K071221).

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Discussion – The environments for use are identical to the predicate AutoMedx SAVe™ (K071221) thus the SAVe II™ basic can be found to be substantially equivalent.

Patient Population –
The SAVe II™ Basic is intended for adult patients greater than 45 kg.
Discussion – The predicate AutoMedx SAVe™ (K071221) was cleared for patients greater than 45 kg, the proposed SAVe II™ Basic fits within the predicate Impact Model 754 (K931473) and thus can be considered substantially equivalent.

Table 3 – Comparison of Proposed SAVe II™ Basic and Predicate AutoMedx SAVe™ K071221)

Features	SAVe II™ Basic	AutoMedx SAVe™ - K071221
Indications for Use	The SAVe II™ series are intended to provide short-term ventilatory support to adults during CPR or when Positive-Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure (ARF). The SAVe II™ series are appropriate for adults that weigh at least 45 kg. It is intended to be used in pre-hospital, field hospitals, and transport environments.	Intended to provide short-term ventilatory support to individuals during CPR or when Positive-Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure (ARF).
Users Population	Qualified and trained users	Qualified and trained users
Patient Population	Adult patients weighing >45 kg	Patients weighing >45 kg
Target Environment	pre-hospital field hospitals hospital transport	pre-hospital field hospitals transport
Breath Type	Volume-targeted Time-cycled Pressure limited	Volume-targeted Time-cycled Pressure limited
Main Ventilation Mode	Assist Control	Assist Control
Basic and Advanced User Modes	No	No
Manual Triggered Breath	No	No
CPR Mode	No	No
Air Source	Ambient / Oxygen	Ambient / Oxygen
TV [mL/breath]	300 – 700 increments of 100	600 (fixed)
RR [br/min]	10 fixed	10 (fixed)
Inspiratory Flow [L/min]	Up to 27	Up to 17
I:E Ratio	Fixed at 1:3 or 1:2	Fixed at 1:2
PIP Limit [cmH2O]	30 fixed	38
PEEP [cmH2O]	0 fixed	0
Supplemental Oxygen (FIO2)	21 – 100%	21 - 60%
Startup Self-Test	Yes	Yes
Circuit Disconnect	Yes	Yes
Over Pressure / Blockage	Yes	Yes
External Power Indicator	Yes	Yes
Low Battery	Yes	Yes
Detect Spontaneous Breath	Yes	Yes

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Features	SAVe II™ Basic	AutoMedx SAVe™ - K071221
Device Temperature Too High	Yes	Yes
Excessive PEEP ("Breath Stacking")	Yes	Yes
I:E Ratio Exceeded	No	No
Source for ventilation	Internal, battery operated compressor	Internal, battery operated compressor
Weight [lbs]	2.6	3.1
Display/User Interface	Membrane Panel, LEDs, and 7-Segment Displays	Rotary Switch, LEDs
Patient Breathing Circuit	Active Breathing Valve	Passive Breathing Valve
Oxygen	Low flow sources, O_2 flow meters, and O_2 concentrators	Low flow source, O_2 flow meter, and O_2 concentrator (up to 10 L/min)
EtCO2 Detector	Yes (External)	Yes (External)
Battery	Rechargeable, Lithium Ion	Rechargeable, Lithium Ion
Duration per charge	10 hrs @TV=600,RR=10,PEEP=0	5.5 hrs @TV=600,RR=10,PEEP=0
External Power Supply	Input: 100 – 240 VAC / 50 – 60 Hz Output: 16.8 VDC	Input: 100 – 240 VAC / 47 – 63 Hz Output: 15 VDC

Technology –

Principle of Operation –
The Save II™ Basic is a battery powered ventilator with an internal compressor which generates the positive pressure to be delivered. It primary gas source is ambient air but supplemental oxygen may be used. It is has integrated software and electronics which control the functions and alarms. The user interface is a membrane panel with LEDs. The patient interface is a standard ventilator circuit that can connect to the patient via a face mask, supraglottic airway, endotracheal tube, or tracheostomy tube.
Discussion – The SAVe II™ Basic and the predicate AutoMedx SAVe™ (K071221) have the identical operating and technological characteristics and modes of operation. The User Interface of the SAVe II™ Basic is a membrane panel which is identical to the predicate.

Alarms –
The SAVe II™ Basic has full complement of alarms expected for a ventilator. These include – circuit disconnect, over pressure / blockage, external power indicator, low battery, detect spontaneous breathing Excessive PEEP, and device temperature too high.
Discussion - The SAVe II™ Basic and the predicate have the same set of alarms.

Non-clinical Testing –

Bench Testing –
We have performed a complete set of performance testing to the device specifications and confirmed that the device meets it performance requirements.

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In addition, we performed durability testing up to 2,000 hours, EMC, EMI, electrical safety, mechanical and environmental testing and Atmospheric Pressure Testing at both 10.15 psia (700 hPa) and 15.95 psia (1100 hPa). The latter represents a simulated altitude of 10,000 feet.
Discussion – We performed a full complement of bench tests that demonstrated that the SAVe II™ which would include the SAVe II™ Basic, met its performance requirements and specifications. It can be considered substantially equivalent to the predicates having undergone similar or identical testing as the predicates.

Substantial Equivalence Conclusion –

The sponsor has demonstrated through performance testing, comparison of design and features, and non-clinical testing that the proposed device and predicate can be found to substantially equivalent.

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

March 21, 2014

AutoMedx, Incorporated
C/O Mr. Paul Dryden
Regulatory Consultant
1420 Lakeside Parkway, Suite 102
Flower Mound, Texas 75028

Re: K131877
Trade/Device Name: SAVe II™
SAVe II™ Basic
Regulation Number: 21 CFR 868.5925
Regulation Name: Ventilator, Emergency, Powered (Resuscitator)
Regulatory Class: II
Product Code: BTL
Dated: February 14, 2014
Received: February 18, 2014

Dear Mr. Dryden:

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 Part 801); 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131877

Device Name
SAVe II™ and SAVe II™ Basic

Indications for Use *(Describe)*

The SAVe II™ series are intended to provide short-term ventilatory support to adults during CPR or when Positive-Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure (ARF). The SAVe II™ series are appropriate for adults that weigh at least 45 kg. It is intended to be used in pre-hospital, field hospitals, and transport environments.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anya C. Harry -S
2014.03.20
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