K132903

JUL 0 1 2014

510(k) Summary
Page 1 of 5
7/1/2014

DRE Medical, Inc.
1800 Williamson Court
Louisville, KY 40026 USA

Tel - 502 244 4444
Fax - 502 244 0369

Official Contact: Mike Spencer CEO

Proprietary or Trade Name: Ventura

Common/Usual Name: gas-machine, anesthesia

Classification Name/Code: BSZ – gas-machine, anesthesia
CFR 868.5160
Class 2

Device: DRE Ventura

Predicate Device: Penlon –Prima K061102

Device Description:
The DRE Ventura anesthetic machine is a constant flow anesthesia gas delivery system intended for human use.

The intended use for the Ventura anesthesia gas delivery machine is for the application of continuous flow anesthesia in a hospital, office based anesthesia settings, induction room or operating room. The units are intended to provide controlled concentrations and flows of anesthesia gases and vapors into a patient breathing system. The anesthesia machine is designed for use by suitably qualified practitioners only.

The basic device is commonly referred to as an anesthesia trolley.

The Ventura is fitted with facilities to deliver 3 gases – oxygen, nitrous oxide or air. Up to 4 'E' size cylinders can be fitted along with pipeline supplies for all gases. It has a number of drawers for storage.

In order to make the unit fully functional, the Ventura can be fitted with FDA cleared equipment, such as:

- Anesthetic agent vaporizer, specifically Selectatec compatible designs
- Carbon dioxide absorber
- Gas scavenging system
- Ventilator of the complete standalone type

The Ventura has an anti-hypoxic device is built into the oxygen gas control system to enable a safe supply anesthetic gases under varying flow conditions.

Indications for Use: The Ventura anesthesia gas delivery machine is designed to deliver a combination of medical gases and volatile anesthetic agents to a breathing system.

Environment of Use: Locations where an anesthesia delivery device may be required.

Patient Population: Adult, the subject device is not indicated for pediatric populations

Contraindications
There are no known contraindications.

Differences between the proposed and predicate devices:
There are a few differences between the proposed Ventura and the predicate. They include:

- Integral oxygen monitor vs. in-line oxygen monitor
  - The oxygen monitor has the same features as the add-on but it is just integrated for convenience of the user.
- Add of secondary pressure regulator for all gases vs. only for oxygen
  - No technological differences
- Difference ancillary components mounting systems GCX type vs. Modura
  - No technological differences

These differences do not pose any significant technological differences nor do they raise any new safety concerns.

Summary of substantial equivalence
The DRE Ventura was compared to the predicate Penlon Prima (K061102) as in the device comparison table below.

Device Comparison Table

	DRE Ventura **Proposed Device**	**Penlon Prima** **510(k)- K061102**
Indications for Use	The Ventura anesthesia gas delivery machine is designed to deliver a combination of medical gases and volatile anesthetic agents to a breathing system.	The Penlon Prima is designed to deliver a combination of medical gases and volatile anesthetic agents to a breathing system.
Environment of use	Locations where an anesthesia delivery device may be required.	Locations where an anesthesia delivery device may be required.
Configurations	The trolley may be configured with up to 3 different gases, oxygen, nitrous oxide and air	The trolley may be configured with up to 3 different gases, oxygen, nitrous oxide and air
Components to be fitted to make it a complete system This components are standalone 510(k) cleared devices	Vaporizers Ventilator Carbon Dioxide absorber Waste Gas Scavenging system (AGSS) Breathing circuit Oxygen monitor (built-in)	Vaporizers Ventilator Carbon Dioxide absorber Waste Gas Scavenging system (AGSS) Breathing circuit Oxygen monitor (separate)
Construction	Structural aluminum extrusions, PU moldings and panels. Aluminum and stainless steel sheet.	Structural aluminum extrusions, PVC moldings and panels. Aluminum and stainless steel sheet.
Gas supplies	Oxygen, Air and/or Nitrous oxide. Pipeline supply or cylinder to ISO standards for pressure, purity and non-interchangeable connections. Inlet 100 micron filters	Oxygen, Air and/or Nitrous oxide. Pipeline supply or cylinder to ISO standards for pressure, purity and non-interchangeable connections. Inlet 100 micron filters

Gas flows	O_2: 200ml – 10 l/min Air: 200ml – 12 l/min N_2O: 200ml – 10 l/min	O_2: 200ml – 10 l/min Air: 200ml – 10 l/min N_2O: 200ml – 10 l/min
Flowmeter position.	Left Hand Side (LHS) of machine. Oxygen control on LHS of flowmeter. N_2O at right extreme position.	LHS of machine. Oxygen control on LHS of flowmeter. N_2O at right extreme position.
Flow tubes	Diameter and length indexed. Oxygen added after all other gasses.	Diameter and length indexed. Oxygen added after all other gasses.
Flowmeter illumination.	Yes	Yes
Low oxygen pressure/concentration alarms.	Yes, Ritchie Whistle system and adjustable 25 – 100% user set. Default 25%. Detected with fuel cell.	Yes, Ritchie Whistle system and adjustable 30 – 100% user set. Default 30%. Detected with fuel cell.
Nitrous cut off system.	Yes, Pressure operated, sprung return cut off spool valve.	Yes, Pressure operated, sprung return cut off spool valve.
Anti Hypoxic system.	Yes, mechanical anti hypoxic link system. Min 23%. Powered by oxygen pressure.	Yes, mechanical anti hypoxic link system. Min 27%. Powered by oxygen pressure.
Air/Nitrous oxide selection switch.	Yes	Yes
Auxiliary gas drive outlets	Yes, Oxygen and Air	Yes, Oxygen and Air
Cylinder pressure reducer.	Single stage brass pressure regulator c/w pressure relief valve safety system.	Single stage brass pressure regulator c/w pressure relief valve safety system.
Secondary pressure regulator	Yes, all gasses.	Yes, O_2 only.
Individual supply pressure gauges	Yes.	Yes.
Internal pipework	Diameter indexed for individual gas supplies	Diameter indexed for individual gas supplies
Low pressure pipework . pressure relief valve at CGO.	Yes, internal	Yes
Vaporizer mounting system.	Selectatec compatible x2. Indexed to prevent non-interlock vaporizers being attached	Selectatec compatible x2. Indexed to prevent non-interlock vaporizers being attached.
O2 flush	Yes, front LHS of machine downstream of all other gasses and vapors.	Yes, front LHS of machine downstream of all other gasses and vapors.
Braked castors	Yes	Yes
Ancillary component mounting system.	GCX type	Modura type
Auxiliary electrical outlet sockets.	Yes x4. Independently fused	Yes x4. Independently fused
Oxygen Monitor	Yes integrated	Required add on
Compliance with Standards	ASTM F1208 – 89 Standard Specification for Minimum Performance and Safety Requirements for Anesthesia Breathing Systems. ISO 8835-2:2007. Inhalational anesthesia systems -- Part 2: Anesthetic breathing systems ASTM F1343 – 02. Standard Specification for Anesthetic Gas Scavenging Systems—Transfer	ASTM F1208 – 89 Standard Specification for Minimum Performance and Safety Requirements for Anesthesia Breathing Systems. ISO 8835-2:2007. Inhalational anesthesia systems -- Part 2: Anaesthetic breathing systems ASTM F1343 – 02. Standard Specification for Anesthetic Gas Scavenging Systems—

	and Receiving Systems ISO 8835-3:2007. Inhalational anesthesia systems -- Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems ISO 8835-4:2004. Inhalational anesthesia systems -- Part 4: Anaesthetic vapor delivery devices ASTM F1101 – 90 (Reapproved 2003). Standard Specification for Ventilators Intended for Use During Anesthesia ISO 8835-5:2004. Inhalational anesthesia systems -- Part 5: Anaesthetic ventilators ISO 5356-1:2004. Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets. Part 1 refers to the connections on the breathing circuit. These connections are not generally used on the machine but they mate with ISO 5356-2:2006. Anaesthetic and respiratory equipment -- Conical connectors -- Part 2: Screw-threaded weight-bearing connectors, which are on the anaesthetic machine. (Dimensional standards)	Transfer and Receiving Systems ISO 8835-3:2007. Inhalational anesthesia systems -- Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems ISO 8835-4:2004. Inhalational anesthesia systems -- Part 4: Anaesthetic vapor delivery devices ASTM F1101 – 90 (Reapproved 2003). Standard Specification for Ventilators Intended for Use During Anesthesia ISO 8835-5:2004. Inhalational anesthesia systems -- Part 5: Anaesthetic ventilators ISO 5356-1:2004. Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets. Part 1 refers to the connections on the breathing circuit. These connections are not generally used on the machine but they mate with ISO 5356-2:2006. Anaesthetic and respiratory equipment -- Conical connectors -- Part 2: Screw-threaded weight-bearing connectors, which are on the anaesthetic machine. (Dimensional standards)

Indications – Equivalent indications

Prescriptive – The DRE Ventura is prescriptive as is the predicate.

Design and Technology – The DRE Ventura has equivalent design and features as the predicate and has the identical technology to the predicate.

Performance and Specifications – The DRE Ventura has equivalent specifications of performance as the predicate.

Compliance with standards – The DRE Ventura and predicate device declare compliance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-13. Additionally, the Ventura complies with ISO 7767

Materials – Materials used are identical to the predicate.

Environment of Use – Same

Patient Population – Adult. The subject device is not indicated for pediatric populations

Performance Testing

We have performed bench tests and found that the DRE Ventura met all requirements specifications and applicable standards requirements and was found to be equivalent in comparison to the predicate. Testing includes:

- Functional Attributes
- Performance Tolerances
- Environmental Conditions
- Compatibility with specified devices
- A variety of performance requirements related to gas flow and oxygen measurement accuracy in compliance with the following performance standards:
    - BS EN 60601-2-13:2006 (IEC 60601-2-13) Medical electrical equipment. Particular requirements for the safety and essential performance of anaesthetic systems.
    - ASTM F 1850 ASTM F1850-00(2005) Particular Requirements for Anesthesia Workstations and Their Components.
    - ISO 21647:2004+Cor 1:2005 Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas Monitors

Conclusion

The DRE Ventura is substantially equivalent to the predicate Penlon Prima (K061102) in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards.

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

July 1, 2014

DRE Medical, Inc.
c/o Paul Dryden
Regulatory Consultant
1800 Williamson Court
Louisville, KY 40026

Re: K132903
Trade/Device Name: DRE Ventura
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: Class II
Product Code: BSZ
Dated: May 29, 2014
Received: May 30, 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.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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)*
K132903

Device Name
DRE Ventura

Indications for Use *(Describe)*

The Ventura anesthesia gas delivery machine is designed to deliver a combination of medical gases and volatile anesthetic agents to a breathing system.

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)*

Todd D. Courtney -S
2014.07.01 10:15:43 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."