May 5, 2017

Sedation Systems LLC
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Paul Dryden
Consultant, Promedic LLC
2471 McMullen Booth Rd, Ste. 316
Clearwater, Florida 33759

Re: K160950
Trade/Device Name: MINISCAV™
Regulation Number: 21 CFR 868.5430
Regulation Name: Gas-Scavenging Apparatus
Regulatory Class: Class II
Product Code: CBN, BTA
Dated: April 27, 2017
Received: May 1, 2017

Dear Paul 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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
K160950

Device Name

MINISCAV™

Indications for Use (Describe)

The MINISCAV™ waste gas evacuation apparatus is intended to remove patients’ exhaled waste gases during procedures where analgesia is administered to a patient via inspiration of mixtures of nitrous oxide and oxygen from a nitrous oxide / oxygen delivery device. Not intended for use with flammable anesthetic gases.

This device is intended for professional use only in healthcare facilities, clinics, and physician and dentist offices.

Type of Use (Select one or both, as applicable)

XX  Prescription Use (Part 21 CFR 801 Subpart D)  ☐  Over-The-Counter Use (21 CFR 801 Subpart C)
Sedation Systems LLC  
2471 McMullen Booth Rd., Suite 316  
Clearwater, FL 33759  
Tel – 888-959-5288  

**Official Contact:** S. Michael Bender, Managing Member  

**Proprietary or Trade Name:** MINISCAV™  

**Common/Usual Name:** Apparatus, Gas Scavenging  

**Classification Name / Product Classification**  
Apparatus, Gas Scavenging  
CBN, 21CFR 868.5430, Class II  

**Predicate Devices:**  
G. Dundas, Active Waste Gas Scavenger System, K110930  
Medela, Dominant Flex Suction Pumps, K150134  

**Device Description:**  
The MINISCAV™ is a small, portable, vacuum pump that generates a constant vacuum that can be connected via a standard flexible vacuum hose to nitrous oxide / oxygen delivery equipment. The vacuum hose is connected to the “vacuum / suction” nipple on exemplary equipment.  

**Indications for Use:**  
The MINISCAV™ waste gas evacuation apparatus is intended to remove patients’ exhaled waste gases during procedures where analgesia is administered to a patient via inspiration of mixtures of nitrous oxide and oxygen from a nitrous oxide / oxygen delivery device. Not intended for use with flammable anesthetic gases.  

This device is intended for professional use only in healthcare facilities, clinics, and physician and dentist offices.

**Table 1 Substantial equivalence Comparison to Predicates**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Predicate G. Dundas Active Waste Gas Scavenger System K110930</th>
<th>Predicate Medela Dominant Flex Suction Pumps K150134</th>
<th>Proposed MINISCAV™</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Classification</strong></td>
<td>CBN CFR 868.5430 Gas scavenging apparatus Class II</td>
<td>BTA CFR 878.4780 Powered suction pump Class II</td>
<td>CBN CFR 868.5430 Gas scavenging apparatus Class II</td>
</tr>
<tr>
<td><strong>Indications for Use</strong></td>
<td>The Waste Gas Scavenger is designed for use with vacuum (suction) waste gas disposal systems with anesthesia machines and heart/lung bypass</td>
<td>The Dominate Flex Suction Pump is indicated for vacuum extraction, aesthetic body contouring, aspiration during flexible endoscopy, and</td>
<td>The MINISCAV™ waste gas evacuation apparatus is intended to remove patients’ exhaled waste gases during procedures where analgesia is administered to a patient</td>
</tr>
</tbody>
</table>
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machines. aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials from wounds or from a patient’s airway or respiratory support system either during surgery or at the bedside.

via inspiration of mixtures of nitrous oxide and oxygen from a nitrous oxide / oxygen delivery device. Not intended for use with flammable anesthetic gases. This device is intended for professional use only in healthcare facilities, clinics, and physician and dentist offices.

Environment of Use

<table>
<thead>
<tr>
<th>Description</th>
<th>Healthcare facilities, clinics and physician and dentist offices.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Used with flammable anesthetic gases</td>
<td>No</td>
</tr>
<tr>
<td>Requires a vacuum source</td>
<td>Yes, connects to any vacuum source Central supply / wall / Portable pump</td>
</tr>
<tr>
<td>Connects a flexible hose from this pump to any device requiring a vacuum source, i.e., gas scavenging apparatus</td>
<td></td>
</tr>
<tr>
<td>Connects a flexible hose from this pump to a gas scavenging apparatus</td>
<td></td>
</tr>
<tr>
<td>Means of connection</td>
<td>A flexible vacuum hose from the device to the vacuum source</td>
</tr>
<tr>
<td>Connects a flexible hose from this pump to any device requiring a vacuum source, i.e., gas scavenging apparatus</td>
<td></td>
</tr>
<tr>
<td>Fittings</td>
<td>19 mm Hose barb for vacuum</td>
</tr>
<tr>
<td>19 mm Hose barb for vacuum</td>
<td></td>
</tr>
<tr>
<td>Vacuum pressures</td>
<td>Can accept a range of applied vacuum as it no range limit specified</td>
</tr>
<tr>
<td>Flow rate</td>
<td>Up to -700 mmHg</td>
</tr>
<tr>
<td>90 mmHg</td>
<td></td>
</tr>
<tr>
<td>42 Lpm +/- 5 Lpm</td>
<td></td>
</tr>
<tr>
<td>Connects to a nitrous oxide/ oxygen flowmeter exhaust port</td>
<td></td>
</tr>
<tr>
<td>Technology</td>
<td>Passive device which requires connection to a vacuum source</td>
</tr>
<tr>
<td>Piston / cylinder design Portable</td>
<td></td>
</tr>
<tr>
<td>Diaphragm design Portable</td>
<td></td>
</tr>
</tbody>
</table>

Substantial Equivalence Discussion -

Table 1 above compares the key features of the proposed MINISCAV™ with the identified predicate and reference to demonstrate that the proposed device can be found to be substantially equivalent.

Indications for Use –
While the indications for use are not identical to that of the predicate device (K110930), the subject device and Dundas predicate are intended to remove waste gases from anesthesia gas machine system.

Discussion – The MINISCAV™ is one part of a waste gas scavenging system. The parts include: (1) a scavenger to titrate exhaust gas flow from the patient circuit, which is connected to (2) a vacuum source. This device is intended to scavenge gas, which the same as the intended use of the predicate Dundas scavenger.

Technology, Construction, Performance –
The MINISCAV™ is a diaphragm hermetically sealed pump with a fixed vacuum flow rate. The inlet line is connected to a flowmeter exhaust port of the nitrous oxide / oxygen delivery equipment which has an exhaust port for scavenging gases. The Dundas scavenger (K110930) is a flowmeter that titrates exhaust flow with wall-supplied vacuum sources. While the Dundas scavenger does not supply the vacuum, both the MINISCAV and Dundas devices validate the ability to expel gases at specified vacuum pressures, mitigating risks associated with failure to vacuum. Therefore, the MINISCAV™ does not raise different concerns of safety or effectiveness for substantial equivalence.

The Medela Dominant Flex Suction Pump (K150134) is pump with an adjustable vacuum flow as high as -700 mmHg. The Medela includes indications to remove gases from respiratory support systems, which the MINISCAV also performs by providing vacuum via a separate gas scavenger. Therefore, both devices are validated for vacuum specifications. Although different technologies (vacuum range -700mmHg compared to -90mmHg) exist, these differences do not raise different questions of safety and effectiveness.

Environment of Use –
The environments of use are similar to the predicate Medela Dominant Flex Suction Pump (K150134) and the Dundas Active Waste Gas Scavenger System (K110930).

Discussion – As the environments of use are similar to the predicate they should be considered substantially equivalent.

Non-Clinical Testing Summary –
We performed testing which evaluated:

- AAMI/ANSI/ES60601-1 for electrical safety
- IEC 60601-1-2 for EMC
- Durability
  - Continuous running demonstrated that the vacuum pump stays within its specifications for at least 10,000 hours
  - Real-time testing of the complete unit supports that the device meets its performance specifications after 2 years use
- Vacuum and Flow testing
  - Testing demonstrates that the device provides a constant vacuum of <=90 mmHg at a constant Flow rate of 42 Lpm +/- 5 Lpm which has been deemed sufficient for scavenging waste gases from nitrous oxide / oxygen delivery equipment
  - Determination of maximum length of exhaust tubing
- Leakage
  - Testing demonstrates that after 2 years the unit has no leaks and meets its performance specifications
- Evaluation in an Oxygen Rich Environment per IEC 60601-1 section 11.2.2.
  - Risk Analysis of critical components, oxygen build-up in housing, and construction and separation of the housing and components support compliance to IEC 60601-1 section 11.2.2, clause 1.b(3).
- Compatibility
  - with Porter, Accutron, and Nitronox analgesia systems.

Discussion of Differences –
The differences between the proposed device and the predicate are:
• MINISCAV™ is intended to scavenge waste gases, which is similar to the Dundas Active Waste Gas Scavenger System (K110930).
• While the intended uses are similar, the Dundas device (K110930) must be connected to a vacuum source (such as the MINISCAV™) to operate.
• Limitation of vacuum. While the Medela Dominant Flex Suction Pump (K150134) has a higher vacuum, for connection to a waste gas scavenger, the vacuum pressure is much lower and within the performance specifications of the proposed device.
  o This lower vacuum range is appropriate for the intended use of scavenging gases.

These differences still allow one to find the subject device substantially equivalent to the predicate devices for the proposed indications for use.

**Substantial Equivalence Conclusion** -
Based upon the presented information the sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate device are substantially equivalent.