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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

Feature	Predicate G. Dundas Active Waste Gas Scavenger System K110930	Predicate Medela Dominant Flex Suction Pumps K150134	Proposed MINISCAV™
Product Classification	CBN CFR 868.5430 Gas scavenging apparatus Class II	BTA CFR 878.4780 Powered suction pump Class II	CBN CFR 868.5430 Gas scavenging apparatus Class II
Indications for Use	The Waste Gas Scavenger is designed for use with vacuum (suction) waste gas disposal systems with anesthesia machines and heart/lung bypass	The Dominate Flex Suction Pump is indicated for vacuum extraction, aesthetic body contouring, aspiration during flexible endoscopy, and	The MINISCAV™ waste gas evacuation apparatus is intended to remove patients’ exhaled waste gases during procedures where analgesia is administered to a patient

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

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 –

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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:

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- 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.
 - 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.