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Mergenet Medical, Inc.
6601 Lyons Rd.
Suite B1-B4
Coconut Creek, FL 33073

Tel - 561-208-6886
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Official Contact: Robert Landis – Director R&D

Proprietary or Trade Name: Trach-Assist

Common/Usual Name: Airway (extension) Connector

Classification Name: Airway (extension) Connector
BZA – 868.5810

Predicate Devices:
K850964 – Sheridan (Teleflex) Double Swivel
K833373 – Sontek Bodai Swivel
K770771 – Hudson RCI (Teleflex) Water Trap
K063125 – ARC Medical HME

Device Description:
Trach-Assist is a simple connector with standard 15 mm fittings permitting connection with an endotracheal tube or tracheostomy tube and the patient wye of a breathing circuit.

The Trach-Assist H has a port for insertion of a suction catheter to remove secretions while Trach-Assist-I uses Closed Suction Catheter system to remove secretions.

Indications for Use:
The Trach-Assist is an airway connector intended to connect between an endotracheal tube or tracheostomy tube and the ventilator circuit or closed suction system. It can assist in removal of patient secretions that may collect in ventilatory tubing.

Patient Population:
Patients with tidal volumes > 200 ml

Environment of Use:
Hospitals, health care facilities, homes

Contraindications:
None

Comparative table:

Features	Proposed Device	Predicate Sheridan Double Swivel K850964	Predicate Sontek Bodai Double Swivel K833373	Predicate Hudson RCI Water trap K770771
Product classification	BZA Airway connector	BZA Airway connector	BZA Airway connector	BYH Water trap
CFR	868.5810	868.5810	868.5810	868.5995
		An airway connector is a device intended to connect a breathing gas source to a tracheal tube, tracheostomy tube, or mask	An airway connector is a device intended to connect a breathing gas source to a tracheal tube, tracheostomy tube, or mask	Tee drain (water trap) is a device intended to trap and drain water that collects in ventilator tubing during respiratory therapy, thereby preventing an increase in breathing resistance
Indications for use	The Trach-Assist is an airway connector intended to connect between an endotracheal tube or tracheostomy tube and the ventilator circuit or closed suction system. It can assist in removal of patient secretions that may collect in ventilatory tubing.	Not available	Not available	Not available
Environment of Use	Home, Hospital, Sub-acute Institutions	Home, Hospital, Sub-acute Institutions	Home, Hospital, Sub-acute Institutions	Home, Hospital, Sub-acute Institutions
Patient Population	Tidal volumes > 200 ml	Not available	Not available	Not available
Contraindications	None	None	None	None
Performance and Design Features				
Placement within the patient circuit	Placed between endotracheal or tracheostomy tube and ventilator circuit wye piece	Placed between endotracheal or tracheostomy tube and ventilator circuit wye piece	Placed between endotracheal or tracheostomy tube and ventilator circuit wye piece	Placed in the exhalation or inhalation limb of the circuit

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Features	Proposed Device	Predicate Sheridan Double Swivel K850964	Predicate Sontek Bodai Double Swivel K833373	Predicate Hudson RCI Water trap K770771
Performance and Design Features (continued)				
Permits direct suctioning of patient secretions	Yes Via a port and use of a standard suction catheter (Trach-Assist H) Allows direct connections of a Closed suction catheter system (Trach-Assist I)	Yes Via a port and use of a standard suction catheter	Yes Via a port and use of a standard suction catheter	N/A
Has a reservoir for collection of secretions	Yes within the housing	No	No	Yes but for water which rains out in the tubing
Standard 15 mm / 22 mm fittings	Yes	Yes	Yes	Yes – 22mm as it fittings in the tubing only
Internal Volume	36 ml – "I" 29.6 ml – "H"	Not available	Not available	N/A as it is not located where it is considered dead space
Resistance to flow	0.12 cm H_2O @ 30 Lpm 0.60 cm H_2O @ 50 Lpm 0.93 cm H_2O @ 70 Lpm Trach-Assist–H highest resistance values	Not available	0.17 cm H_2O @ 30 Lpm 0.66 cm H_2O @ 50 Lpm 0.95 cm H_2O @ 70 Lpm **Predicate ARC Medical HME K063125**	N/A
Duration of use	Single patient use up to 24 hours	Single patient use, not specified	Single patient use, not specified	Single patient use, not specified
Provided clean, Non-sterile	Yes	Yes	Yes	Yes

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Differences Between Other Legally Marketed Predicate Devices:

- The Trach-Assist is designed with a reservoir where secretions may collect instead of staying within the patient circuit. This feature is similar to an in-line water trap which keeps water from collecting in the patient circuit and increasing resistance. Except in this case we are collecting secretions.
- We do not believe that this difference is significant and raises any no new patient safety issues.

The proposed device is viewed as substantially equivalent to the predicate devices, K850964, K833373, K770771, and K063125.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 5 2009

Mergenet Medical
C/o Mr. Paul Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

Re: K083702
Trade/Device Name: Trach-Assist
Regulation Number: 21 CFR 868.5810
Regulation Name: Airway Connector
Regulatory Class: I
Product Code: BZA
Dated: December 12, 2008
Received: December 15, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: _____ (To be assigned)

Device Name:

Indications for Use: The Trach-Assist is an airway connector intended to connect between an endotracheal tube or tracheostomy tube and the ventilator circuit or closed suction system. It can assist in removal of patient secretions that may collect in ventilatory tubing.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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