K040507

MAR - 4 2004

510(k) SUMMARY

The Summary of Safety and Effectiveness information on the TAGA Velocity Humidifier with Velocity Humidifier Heater TM1000H is being submitted in accordance with the requirements of 21 C.F.R. §807.92 and reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant **Telephone** **Facsimile**	Gary Austin TAGA Medical Technologies, Inc. 34675 Vokes Dr., Suite 105 Eastlake, Ohio 44095 440/602-8242 440/602-6989
Date	September 19, 2003
Name	TAGA Velocity Passover Humidifier with Velocity Humidifier Heater TM1000H
Classification	Respiratory gas humidifier, 21 CFR 868.5450
Predicate:	TAGA Medical Technologies, Inc., Velocity Passover Humidifier, K031179 market clearance date July 17, 2003, which is used as a component for the new Velocity Humidifier Heater TM1000H device and the Sunrise Medical HHG, Inc. Devilbiss Model 9200D heated Humidfier System, K020900, market clearance date June 03, 2002.
Description	**The following is a summary of the Velocity Passover Humidifier component for the new Velocity Humidifier Heater TM1000H device.** The non-sterile Velocity Passover Humidifier is a plastic housing comprised of two (2) halves, a top and bottom, assembled together to form an enclosed reservoir. An O-ring forms a seal between the two halves when assembled, with a plurality of slide latches maintaining the proper position and seal tensions between the two housing components. The reservoir has two ports, an inlet and an outlet, on the upper portion, both being 22 mm conical connectors, which allow for the connection of commonly used respiratory Continuous Positive Airway Pressure (CPAP) or Bi-level Positive Airway Pressure (BiPAP) flexible tubing. The inlet and outlet port are clearly identified on the device. The inlet port is typically attached to the pressure generating CPAP or BiPAP unit by means of a short piece (12" to 24") of tubing that is supplied with the humidifier. The air entering the humidifier is directed over the surface of the water in the basin through a series of baffles. The design intent of the baffles shape and placement is to create turbulence in the airflow over the water surface. The baffles also create an eddy effect, which in turn increase the duration that the air is exposed and travels across the surface of the water. The combination of both of these effects maximizes the evaporation process thereby elevating the humidity level of the gas before exiting the device. The air exits the device through the outlet port into a second piece of tubing supplied by the user that is connected the patients' mask. The volume of water is sufficient to provide 10 hours minimum use at 70 °F and 25% RH ambient conditions and a patient flow rate of 90 LPM. The humidifier is filled only when removed from the CPAP or BiPAP systems. The Passover Humidifier is used in a horizontal position and will act as a base for most marketed CPAP or BiPAP systems. This feature

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	ensures that the water level is below the outlet port on the CPAP or BiPAP systems to eliminate the potential hazard of water reaching any CPAP or BiPAP electrical components. **The following is a description for the new Velocity Humidifier Heater TM1000H component of the device.** The Velocity Humidifier Heater TM1000H consists of a plastic housing with an On/Off switch, control knob, heater plate assembly and two indicator LEDs. The Velocity passover humidifier rests on the heater plate assembly. The heater plate assembly operates at a scale of low (88°F (31°C)) to high (140°F (60°C)) as selected by the user by adjusting the control knob. The Velocity humidifier heater contains a built-in safety device to prevent the heater plate from reaching excessive temperatures under fault conditions. If the heater plate temperature exceeds approximately 90° C (194° F) power to the unit is terminated. The device has an electrical rating of 110 volts 60Hz, 110 Watts. The device works by heating a metal plate that the plastic humidifier rests on. This in turn warms the water within the humidifier. As the air flows over the water, it picks up some of the moisture. As a result, the gas exiting the humidifier is warmed and humidified providing a continuous humid air stream gas to the patients that require continuous humid positive airway pressure. The system controls the temperature of the heater plate assembly only and not the water or gas temperature.
Intended Use	The TAGA Velocity Passover Humidifier with Velocity Humidifier Heater TM1000H is a respiratory positive airway pressure accessory intended to add moisture to the air stream gases for administration to the patient. The humidifier can be used with standard CPAP and or Bi-level Positive Airway Pressure (BiPAP) devices, which have a maximum operating pressure of 20 cm H_20, and do not have automatic pressure titration capabilities. **Environment of Use / Patient Population** For single patient use in home, physician's office or hospital / institutional environment.
Warning:	• Disconnect the air tubes prior to cleaning, water entering the CPAP unit may result in electric shock hazard or damage to the CPAP unit. • Do not use bleach or chlorine based solutions to clean the humidifier or tubing. • The humidifier is for single-patient use only. • The Velocity Humidifier can be used with CPAP or Bi-level CPAP devices which have a maximum operating pressure of 20 cm H_2O, and do not have automatic pressure titration capabilities.

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Caution:	• Federal law (U.S.A.) restricts this device to sale by or on the order of a physician. • Do not expose the tubing to direct sunlight as it may deteriorate over time. • Replace the humidifier if any sign of damage to the chamber or leaking appears. • Not recommended for use with auto-titrating (adjusting) CPAP device unless otherwise stated by the CPAP device. • The heater is only for use with the Velocity Humidifier.
Technological Characteristics:	The Velocity Humidifier Heater TM1000H relative humidity gain matched or exceeded the Devilbiss relative humidity gain at all flows and temperature settings.
Standards:	The subject device conforms to the following voluntary standards: EN/IEC/UL 60601-1 — Medical electrical equipment, *Part 1: General requirements for safety* EN/IEC/UL 60601-1-2 — Medical Electrical Equipment—*Part 1: General Requirements for Safety, Amendment No. 2. Collateral Standard: Electromagnetic Compatibility Requirements and Tests*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 4 2004

Mr. Gary Austin
Vice President
Taga Medical Technologies
34675 Vokes Drive
Suite 105
Eastlake, Ohio 44095

Re: K040507
Trade/Device Name: Taga Velocity Passover Humidifier with Heater, Model TM1000H
Regulation Number: 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: February 26, 2004
Received: February 27, 2004

Dear Mr. Austin:

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 Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Chiu Lin, Ph.D.
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

510(k) Number (if known): K040507

Device Name: **TAGA Velocity Passover Humidifier with Heater**

Indications For Use:

The TAGA Velocity Passover Humidifier with Velocity Humidifier Heater TM1000H is a respiratory positive airway pressure accessory intended to add moisture to the air stream gases for administration to the patient. The humidifier can be used with standard CPAP and or Bi-level Positive Airway Pressure (BiPAP) devices, which have a maximum operating pressure of 20 cm H_2O, and do not have automatic pressure titration capabilities.

Environment of Use / Patient Population
For single patient use in home, physician's office or hospital / institutional environment.

Prescription Use **X** AND/OR Over-The-Counter-Use _____
(Per 21 CFR 801 Subpart D) (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

510(k) Number: K040507