K031179

Attachment 2 – 510(k) Summary

The Summary of Safety and Effectiveness on the TAGA Velocity Humidifier 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. . 7561 Tyler Road, Unit 8 Mentor, Ohio 44060 440/953-9605 440/953-9602
Date	April 11, 2003
Name	TAGA Velocity™ Passover Humidifier
Classification	Respiratory gas humidifier, 21 CFR 868.5450, 73BTT
Predicate:	TAGA Velocity™ Humidifier, (K#010578) Devilbiss 9100D (K#003626)
Description	The TAGA Velocity Passover Humidifier is a plastic housing comprised of two (2) halves permanently joined to form an enclosed reservoir. 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 CPAP flexible tubing. The inlet and outlet port are clearly identified on the device. The inlet port is typically attached to the pressure generating CPAP 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 humidifier is filled with distilled or sterile water through either the inlet or outlet ports with the unit held in an upright position. The humidifier has a window with markings to allow the user to fill with the appropriate volume. The unit is manufactured out of a transparent plastic that allows the user to visually verify the volume level at all times. 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 system. The humidifier is used in a horizontal position and will act as a base for most marketed CPAP systems. This feature ensures that the water level is below the outlet port on the CPAP system to eliminate the potential hazard of water reaching any CPAP electrical components. The humidifier's moisture gain output exceeds 10mg H2O/L as required by ASTM F1690-96 and ISO 8185:1997. The maximum pressure drop throughout the range of flow rates does not exceed 2kPa per ASTM F1690-96 and ISO 8185:1997. The Velocity humidifier will be cleaned daily by hand washing with a mild dish washing and warm water solution and weekly by soaking in a 25% vinegar/water solution for 30 minutes, both followed by a clean water rinse.
Intended Use	The TAGA Velocity humidifier is a respiratory Continuous Positive Airway Pressure (CPAP) accessory intended to add moisture to the airstream gases for administration to the patient. The humidifier increases the vapor content of the air as it passes through the device (passover) and is directed by the array of baffles over the surface of a body of water. The humidifier can be used with standard CPAP devices which have a maximum operating pressure of 20 cm H_2O, and do not have bi-level or automatic pressure titration capabilities.
Warning: **Caution:**	• 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 humidifier can be used with BiPAP and or CPAP devices which have a maximum operating pressure of 20 cm H_2O, and do not have automatic pressure titration capabilities. • 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. • Do not mix the solution of vinegar with any disinfectants to clean the humidifier or tubing. • Replace the humidifier if any sign of damage to the chamber or leaking appears.
Technological Characteristic	AAMI TIR No. 12 – 1994; Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers. Low Level Disinfection. Pressure Range: 3 – 20 cm H_2O — Reservoir Capacity: 600 ml Relative Humidity Output: > 25% — Operating Duration: 10 Hours @ 70° F, 25% RH Operating Temperature: 5° to 40 ° C — Storage Temperature: -20° to 60 ° C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2003

Mr. Gary Austin
Vice President
TAGA Medical Technologies. Inc.
34675 Vokes Dr., Ste. 105
Eastlake, OH 44095

Re: K031179
Trade/Device Name: TAGA Velocity Humidifier
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: April 14, 2003
Received: April 15, 2003

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,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 1 – Statement of Indications for Use

510(k) Number: _____

Device Name: TAGA Medical Technologies Inc. Velocity™ Humidifier

Intended Use / Indications for Use:

The TAGA Velocity™ Passover humidifier is a respiratory positive airway pressure accessory intended to add moisture to the airstream gases for administration to the patient. The humidifier increases the vapor content of the air as it passes through the device (Passover) and is directed by the array of baffles over the surface of a body of water. 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 H2O, 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.

(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: K031179

Prescription Use ✓ OR Over the Counter Use ___
(per 21 CFR 801.109) Optional Format 1-2-96