8. 510(k) Summary – Date 09/10/2010

In accordance with 21 CFR section 807.92 Atlantean is submitting the following 510(k) summary.

8.1. Submitter Information

Atlantean Corporation
1F, No. 789, Bo-ai St., Chubay City
Hsinchu County 302, Taiwan

Tel. 886-3-555-8340

Owner/Operator No.: 10033507

8.2. Preparer of Submission and Contact for Information

MD*Ventures*
Tom Shanks* – Principal
29201 Via Norte
Temecula, CA 92591

Phone: (951) 506-2674
FAX: (951) 506-3040
E-mail: tom@mdventures.net

8.3. Name of Device

Proprietary Name:	Trigger Nebulizer
Common Name:	Nebulizer
Classification Name:	Nebulizer (direct patient interface)
Product Code:	CAF
Regulation Number:	868.5630
Device Class	2

8.4. Substantially equivalent to:

- Hudson RCI Micro Mist (K930525)

8.5. Description of the device

The Atlantean Trigger Nebulizer is used to administer various aerosol treatments in both the homecare and hospital settings. This device is intended to only be use with FDA-approved drugs upon the specific direction of a physician. This device is not used with a specific drug nor is it distributed with such drugs.

The nebulizer has a trigger that allows the patient or clinician to activate the nebulizer which then generates respiratory size aerosolized liquids into gasses that are delivered directly to the patient for breathing. This trigger function conserves medication and reduced environmental contamination by medication. This nebulizer is also available with an attachable BFE/VFE filter that connects to the exhalation port of the nebulizer.

8.6. Intended Use of the Device

The Atlantean Trigger Nebulizer is used to administer various aerosol treatments in both the homecare and hospital settings. This device is intended for use only with FDA-approved drugs upon the specific direction by a physician. Its use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using a Small Volume Nebulizer.

8.7. Comparison to Predicate Devices

Similarities:

- The Atlantean Trigger Nebulizer (see Figure 1) utilizes equivalent, materials, principles of aerosol generation, and intended use are identical.
- With the trigger in the locked position the Atlantean Trigger Nebulizer operates as a continuous mode.

Differences:

- The Atlantean Trigger Nebulizer incorporates a trigger mechanism that allows the patient or clinician to activate the nebulizer which then sprays respiratory size aerosolized liquids into gasses that are delivered directly to the patient for breathing. This trigger function conserves medication and reduced environmental contamination of medication.
- The Atlantean Trigger Nebulizer enhances the performance by drawing inhaled air through the nebulizer as opposed to the Hudson RCI Micro Mist in which inhaled air passes through a Nebulizer Tee and aerosol tubing which acts as an aerosol reservoir.
- The Atlantean Trigger Nebulizer also is available with an attachable BFE/VFE filter that connects to the exhalation port of the nebulizer.

Performance testing:

Atlantean Trigger Nebulizer was found to have improved respirable mass overall and treatment times at 5LPM and than the predicate device. All other attributes were not found to be significantly different than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL - 1 2011

Atlantean Corporation
C/O Mr. Tom Shanks
Principal
MDVentures
29201 Via Norte
Temecula, California 92591

Re: K102719
Trade/Device Name: Atlantean Trigger Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: June 21, 2011
Received: June 23, 2011

Dear Mr. Shanks:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Anthony D. Watson, B.S., M.S., M.B.A.
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):

Device Name: Atlantean Trigger Nebulizer

Indications for Use:

The Atlantean Trigger Nebulizer is used to administer various aerosol treatments in both the homecare and hospital settings. This device is intended for use only with FDA-approved drugs upon the specific direction by a physician. Its use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using a Small Volume Nebulizer.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dan G. Allen for Lee Schultheiss, MD, PhD

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K102719