DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 28, 2016

Athena GTX
Mr. Sean Mahoney
V.P. Regulatory Affairs
5900 NW 86th Street, Suite 300
Johnston, Iowa 50131

Re: K153459
Trade/Device Name: TACVAC™
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: November 25, 2015
Received: December 1, 2015

Dear Mr. Mahoney:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K153459

Device Name: TACVAC Portable Battery Powered Suction Device

Indications for Use:

The TACVAC™ portable battery powered suction device is intended to provide a battery powered medical suction source to clear bodily fluids and particulate matter from a patient. The primary intended use is to clear the airway by removing bodily fluids (including blood, saliva, mucous, vomitus or other aspirant) and particulate matter (less than 0.100"/2.50mm in diameter). The typical use environment is a pre-hospital in the field setting, transport, hospital and other healthcare applications by trained health care providers (EMTs, nurses, doctors, first responders, etc.). The patient population includes adults.

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary of Safety and Effectiveness

510(k) Summary of Safety and Effectiveness

Submitter: Athena GTX
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Date Prepared: January 27, 2016

Trade Name: TACVAC™

Common Name: Portable Battery Powered Suction Device

Product Code: BTA

Classification Regulation: 21 CFR 878.4780

Classification Name: Powered Suction Pump

Device Class: Class II

Basis for Submission: New Device

Legally Marketed (Predicate) Device: S-SCORT... Jr® Quickdraw, Model 2400, (K041154)

Device Description:

The TACVAC™ portable battery powered suction device is designed for the same application and intended use as the SSCOR, Inc. Jr® Quickdraw, Model 2400 listed predicate device. The TACVAC™ portable battery powered suction device is capable of the same functions as have been provided by the predicate device referenced above. The TACVAC™ consist of both re-useable and disposable (one-time use components). The device is very light weight (8 ounces) and can be compactly stowed (7.25” x 7.38” x 3.0”) by inserting the suction unit inside the bottle to reduce space required to carry the device to the point of injury. To assemble from the stowed condition the valve unit is simply removed (unscrewed from the bottle) and the suction unit is removed. Then the valve unit is replaced back on the bottle and the suction unit is inserted into the valve unit and locked in place by twisting to engage the bayonet fittings. The assembled size is 7.25” x 11.88” x 3.0”. A third party suction tip is installed on the suction tubing and then the unit can be turned on/off with the power switch. Once the unit is switched on suction will build in the bottle. Suction is applied at the suction tip by depressing the

510(k) Summary of Safety and Effectiveness

suction button. The device must be kept upright during use to prevent the overfill float check valve from engaging and shutting off suction to the tip. Once the user has finished using the device on a particular patient the valve unit, bottle and suction tip are discarded. The Suction unit is to be cleaned and disinfected. New batteries are installed as required to ensure full suction and use time. A new valve unit, bottle and suction tip are needed for the next use of the device.

Device Indications for Use:

The TACVAC™ portable battery powered suction device is intended to provide a battery powered medical suction source to clear bodily fluids and particulate matter from a patient. The primary intended use is to clear the airway by removing bodily fluids (including blood, saliva, mucous, vomitus or other aspirant) and particulate matter (less than 0.100"/2.50mm in diameter). The typical use environment is a pre-hospital in the field setting, transport, hospital and other healthcare applications by trained health care providers (EMTs, nurses, doctors, first responders, etc.). The patient population includes adults.

Differences in Intended Use between the Device and Predicate:

The TACVAC™ has a more detailed description of the types of fluids and particulate matter that can be suctioned by the device in the Indications for Use statement than the predicate. TACVAC™ also is more descriptive in the use environments and patient population. In all these cases the TACVAC™ provides additional information, but is inclusive of the predicate indications.
The predicate indications statement includes specific information on the device being non-sterile and a single use disposable canister with integrated suction tip. The TACVAC™ does not have non-sterile in the indications statement, but this information is included in the labeling.
These differences are not critical to the intended use and do not affect the safety and effectiveness of the device since they essentially provide more details on use or are the same and included in different locations (Indications Statement vs. Labeling).

Summary of Technological Characteristics:

Similarities: The TACVAC™ portable battery powered suction device employs the same technology as the predicate device including: battery powered portable suction, hand held during operation, suction provided via a diaphragm vacuum pump, enclosures are constructed of plastic material, protection against fluid overflow, and electrical circuit protection.

Differences: The differences between the TACVAC™ and predicate device include: the TACVAC™ uses a larger non-custom collection container and the predicate device uses a custom collection container, the TACVAC™ has a fixed vacuum setting (medium) and the predicate has two settings (high and low), the TACVAC™ is smaller and lighter than the predicate, the TACVAC™ has an additional reverse voltage protection circuit, the

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TACVAC™ uses a lower voltage Lithium based battery and the predicate uses a higher voltage sealed lead-acid or alkaline battery, and the TACVAC™ has a reported longer 200mL simulated vomitus suction time.

Summary of Non-Clinical Performance Testing:

The TACVAC™ portable battery powered suction device employs the substantially equivalent performance as the predicate device including: Vacuum and Flow rating, similar operational times, environmental ratings and the same IPX4 rating. Testing of the TACVAC™ Portable Battery Powered Suction Device has been completed to verify compliance with recognized national and international standards for safety and performance for medical devices, and particular requirements applicable to this device including:

IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance and

IEC 60601-1-2 Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.

Additionally the following tests per ISO 10079-1 were also performed: Mechanical strength (Drop height), vibration and noise, means to prevent inadvertent contamination of the pump, fluid ingress protection, environmental (temperature and humidity), medium vacuum, pharyngeal suction (simulated vomitus), and minimum battery life test.

Summary of Clinical Performance Testing: (none)

Conclusion:

Based on the results for all safety and compliance testing performed, it is the opinion of Athena GTX the TACVAC™ Portable Battery Powered Suction Device is safe and effective, and is substantially equivalent to the above listed predicate device.