DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 22, 2015

Wound RX Medical, LLC
Richard Deslauriers, M.D.
Chief Executive Officer
25 Depot Road, Building One, Suite 104
Southbury, Connecticut 06488

Re: K142385
Trade/Device Name: Whisper Pump System™
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: April 20, 2015
Received: April 22, 2015

Dear Dr. Deslauriers:

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" (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 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,

David Krause -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142385

Device Name
Whisper Pump System™

Indications for Use *(Describe)*
The Whisper Pump System™ is a suction device intended for aspiration and collection of secretions and body fluids from wounds and is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing. Whisper Pump System™ is appropriate for use on the following wounds:

- Pressure ulcers
- Diabetic/neuropathic ulcers
- Venous insufficiency ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Explored fistulas
- Skin flaps and grafts

Contraindications
The use of the Whisper Pump System™ is contraindicated in the presence of:
- Eschar
- Untreated osteomyelitis
- Malignancy in wound (with the exception of palliative care to enhance quality of life)
- Untreated malnutrition
- Exposed , arteries, veins or organs
- Necrotic tissue
- Non-enteric unexposed fistulas
- Exposed nerves
- Exposed anastomotic sites
- Exposed bone or tendons
- Exposed vasculature

The Whisper Pump System™ is not designed for use with emergency medical services.

Not to be used:
- In non-medical applications
- In presence of combustible or explosive fluids or gases

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Contact: Richard Deslauriers, M.D.
CEO, Wound RX Medical, LLC
(203) 982 – 4239

Device Trade Name: Whisper Pump System™

Common Name: Powered suction pump

Manufacturer: Wound RX Medical, LLC
25 Depot Road
Building One, Suite 104
Southbury, CT 06488

Date Prepared: May 12, 2015

Classification: 21 CFR §878.4780; Pump, portable, aspiration (manual or powered)

Class: II

Product Code: OMP

Indications For Use: The Whisper Pump System™ is a suction device intended for aspiration and collection of secretions and body fluids from wounds and is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing. Whisper Pump System™ is appropriate for use on the following wounds:

- Pressure ulcers
- Diabetic/neuropathic ulcers
- Venous insufficiency ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Explored fistulas
- Skin flaps and grafts

Contraindications
The use of the Whisper Pump System™ is contraindicated in the presence of:

- Eschar
- Untreated osteomyelitis

- Malignancy in wound (with the exception of palliative care to enhance quality of life)
- Untreated malnutrition
- Exposed , arteries, veins or organs
- Necrotic tissue
- Non-enteric unexposed fistulas
- Exposed nerves
- Exposed anastomotic sites
- Exposed bone or tendons
- Exposed vasculature

The Whisper Pump System™ is not designed for use with emergency medical services.

Not to be used:

- In non-medical applications
- In presence of combustible or explosive fluids or gases

Prescription-Use Only: Federal law restricts the sale by or on the order of a physician.

Device Description:

The Whisper Pump System™ is a device to remove bodily fluids for wound drainage and can be used by patients over an extended period of time as recommended by a physician. The device has a rechargeable battery and therefore is portable. A microprocessor controlled electronic battery charging unit in the suction device guarantees the safe charging of the battery, and overcharging of the battery. The Whisper Pump System™ itself is not a sterile device but can use disposable (sterile) items from other manufacturers but these items are not a part of the Whisper Pump System™, (e.g. various hose sets, containers, trocars and catheters) which have been designed for the wound drainage.

The purpose of this traditional 510(k) was to modify the outer case dimensions, carrying handle ergonomics, canister bracket, and internal component reconfiguration.

Predicate Device: The predicate information is summarized in the following table.

510(k) Number	K090130
Device Name	ATMOS S041 Wound™
Applicant	ATMOS Medical, Inc.
Regulation Number	21 CFR §878.4780
Classification Product Code	OMP
Decision Date	04/02/2009
Decision	Substantially equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery

Reference Device: The following device was included as a reference device. It was not used to establish substantial equivalence.

510(k) Number	K061367
Device Name	BlueSky Vista Wound Vacuum
Applicant	Blue Sky MG, Inc
Regulation Number	21 CFR §878.4780
Classification Product Code	OMP
Decision Date	08/10/2006
Decision	Substantially equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery

Technological Characteristics:

The Whisper Pump System™ is a small suction unit. The device is operated by an electromotive membrane pump which is maintenance-free. When it operates, the pump creates a vacuum in the hose system and in the collection jar, with the help of which secretions can be sucked off through the set of hoses. The pump switches off after creation of the vacuum and then switches on again when the vacuum lies below a certain value.

The secretion is collected in a collection jar. A hydrophobic bacterial filter prevents the secretion being inadvertently drawn into the pump head. The device is fitted with a rechargeable battery. A microprocessor controlled electronic charging unit in the suction device guarantees the safe

charging of the battery, and thus overcharging of the battery is avoided. The electronic unit prevents overheating of the suction device by a high temperature switch. For the mobile use a carrying strap is available. Useful accessories are a shoulder bag and a device support.

The Whisper Pump System™ is substantially equivalent to other legally marketed devices in the United States and functions in a manner similar and is intended for the same use as the predicate device.

Performance Testing: The risk analysis demonstrates the Whisper Pump System™ is substantially equivalent to the predicate device. The purpose of this 510(k) was to modify the external plastic shell dimensions to reduce the size of the pump. Performance testing involved comparing the device to the predicate device for radiated emission, electrostatic discharge immunity, and thermal protection following IEC60601-1-2 (2014). Previous testing performed on the device is listed below.

A software verification test and product validation test was performed and meet the acceptance criterion. The Whisper Pump System™ have been designed and tested to applicable safety standards (see next page) and does not raise any new issues of safety, efficacy, or performance of the product.

Number of standard	Std Date	Title of standard
ISO 10993-1:1998	1998	Biological Compatibility of medical devices – Part 1: Evaluation and Testing (No biocompatibility tests are needed because device does not have parts that would normally touch patient.)
EN 60601-1-2 (2001)	2001	Medical electrical equipment -- Part 1-2: General requirements for safety -Collateral standard: Electromagnetic compatibility - Requirements and tests
EN ISO 61000-3-2 (2000):	2000	Electromagnetic compatibility - Part 3-2: Limits - Limits for Harmonic current emissions (equipment input current < 16A per phase).
EN ISO 61000-3-3 (1995) + A1 (2001)	1995 2001	Electromagnetic compatibility - Part 3: Limits - Section 3: Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current < 16A.
CEN EN 980:1996+A1:1999+A2:2001	1999 2001	Graphical symbols for use in the labeling of medical devices
EN ISO 14971	03/2001	Medical devices – application of risk management to medical devices
IEC 60601-1	1998, 1991, 1995	Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995. (General)

Conclusion: The Traditional 510(k) for the Whisper Pump System™ contains adequate information and data to enable FDA to determine substantial equivalence to the predicate device. The device will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.