December 30, 2021

Lightstone Medical Products (Ningbo) Co Ltd
% Ruth Wu
Consultant
Lightstone Medical
1820 Ave M, Ste 238
Brooklyn, New York 11230

Re: K202898
Trade/Device Name: Tzoar 207 Negative Pressure Wound Therapy (NPWT) System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 25, 2021
Received: November 19, 2021

Dear Ruth Wu:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Tzoar 207 Negative Pressure Wound Therapy (NPWT) System

Indications for Use *(Describe)*
The Tzoar Negative Pressure Wound Therapy (NPWT) System is indicated for wound management via the application of negative pressure to the wound by the removal of wound exudate, infectious materials, and tissue debris from the wound bed. The Tzoar 207 Negative Pressure Wound Therapy (NPWT) System is indicated for the following wound types: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

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.

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Submitter:

Lightstone Medical Products (Ningbo) Co Ltd.

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Phone: +86 574 56579003

Contact Person: Julian Zhu

Date Prepared: September 24, 2020

Device:

Common Names: Negative Pressure Wound Therapy Device

Proprietary Name: Tzoar 207 Negative Pressure Wound Therapy (NPWT) System

Regulation Number: 21 CFR 878.4780

Classification Name: Negative Pressure Wound Therapy Powered Suction Pump

Regulatory Class: II

Product Code: OMP

Predicate Devices:

The Tzoar 207 Negative Pressure Wound Therapy System is substantially equivalent to the following:

Predicate Device	Manufacturer	510(k)#
extriCARE 3600	Devon Medical	K132225

Device Description

The Tzoar 207 Negative Pressure Wound Therapy (NPWT) System includes a pump and two types of dressings: Tzoar NPWT Foam Kits and Tzoar NPWT One Piece Dressing.

The Tzoar 207 NPWT pump is a portable, battery powered pump which may promote wound healing through the drainage and removal of wound exudates,

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infectious material, and tissue debris from the wound bed using continuous and/or intermittent negative pressure.

The Tzoar NPWT One Piece Dressing and the Tzoar NPWT Foam Kits are both Tzoar Wound Dressings intended to be used with an NPWT device to manage acute and chronic wounds. Patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, diabetic ulcers, neuropathic ulcers, pressure ulcers, flaps and grafts may benefit from this system.

The Tzoar 207 NPWT pump and Tzoar Wound Dressings are able to produce a negative pressure environment in either Continuous or Intermittent Mode. This allows the user to program the specific pressure ranges. In Continuous Mode, the pressure is ranged from 40mmHg to 200mmHg. In Intermittent Mode, the pump will alternate between the up pressure for 5 continuous minutes and down pressure for 2 minutes. The up pressure can be selected between 40 and 200mmHg while the down pressure can be selected between 20 and 120 mmHg. The pressure is applied to the wound as long as the pump is powered on based on the previous settings. The factory default is 125 mmHg in Continuous Mode, unlocked.

Indication for Use:

The Tzoar 207 Negative Pressure Wound Therapy (NPWT) System is indicated for wound management via the application of negative pressure to the wound by the removal of wound exudate, infectious materials, and tissue debris from the wound bed. The Tzoar 207 Negative Pressure Wound Therapy (NPWT) System is indicated for the following wound types: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

Contraindications:

The Tzoar 207 NPWT System should NOT be used in the following conditions:

- Exposed vessels, organs, or nerves.
- Anastomotic sites.
- Exposed arteries or veins in a wound.
- Fistulas, unexplored or non-enteric.
- Untreated osteomyelitis.
- Malignancy in the wound.
- Excess amount of necrotic tissue with eschar.
- Wounds which are too large or too deep to be accommodated by the dressing.
- Allergy to urethane dressings and adhesives.

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- Use of topical products which must be applied more frequently than the dressing change schedule allows.

Technological Characteristics:

The manufacturer believes that the technological characteristics of the Tzoar 207 Negative Pressure Wound Therapy (NPWT) System are substantially equivalent to those of the predicate device. The Tzoar 207 NPWT System has similar components to its predicate device and has similar principles of operation.

The Tzoar 207 NPWT Pump consists of an electrically generated source of vacuum and a canister. Like the predicate, vacuum, is applied for a specified period of time and intensity, according to the physician's prescription.

Both Tzoar NPWT Foam Kits and Tzoar NPWT One Piece Dressings are alternatively used together with the Tzoar 207 NPWT pumps. The Tzoar NPWT Foam Kits and Tzoar NPWT One Piece Dressings use similar components and similar principles of operation to the predicate device. Like the predicate, the foam is placed into the wound and attached to a vacuum device to provide negative pressure to the wound site to promote healing by removing wound exudates.

Performance Tests

To verify that the device design meet its function and performance requirements, samples of the device underwent function and mechanical testing.

The following tests were conducted:

Test Report No.	Test Report Title
TR27.0006	Tzoar 207 NPWT Canister Presence Sensor Test Report
TR27.0007	Tzoar 207 NPWT Canister Hook Test
TR27.0008	Tzoar 207 NPWT Canister Air-Tightness Test
TR27.0010	Tzoar207 NPWT Canister Air filter water resistance verification Test
TR27.0011	Tzoar 207 NPWT Canister Solidifier Expansion Parameter Test Report

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TR27.0013	Tzoar 207 NPWT System Pressure Accuracy Test Report
TR27.0014	Tzoar207 NPWT System Air Flow Rate Test
TR27.0025	Tzoar 207 NPWT System performance test with One Piece Dressing Test
TR27.0027	Tzoar 207 NPWT System Performance test with Foam Kit
TR27.0032	Tzoar 207 NPWT System Battery Life Test Report
TR27.0033	Tzoar 207 NPWT System Battery Performance Testing Report

The conclusions drawn from the performance tests demonstrate that the device is performing as intended and is substantially equivalent to the predicate.

Biocompatibility

Biocompatibility tests were conducted according to the following standards:

- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-6:2016 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC tests were conducted according to the following standards:

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012(or IEC 60601-1:2012 reprint) Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

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- IEC 60601-1-6:2010+A1:2013 Medical Electrical Equipment –Part 1-6 General Requirements for Basic Safety and Essential Performance –Collateral Standard: Usability
- IEC 60601-1-11:2015 Medical Electrical Equipment –Part 1-11 General Requirements for Basic Safety and Essential Performance –Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems used in the Home Healthcare Environment

Statement of Substantial Equivalence

The Tzoar 207 Negative Pressure Wound Therapy (NPWT) System is substantially equivalent in technology, function, operating parameters, and indication for use to the predicate device that is currently commercially available and in distribution, and does not raise any new questions of safety or effectiveness.

Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this pre-market notification, Lightstone Medical Products (Ningbo) Co Ltd believes that the Tzoar 207 Negative Pressure Wound Therapy (NPWT) System is substantially equivalent to the predicate device extriCARE 3600 (K132225) as described herein.

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