March 27, 2019

Baymax Research, Inc.
Richard Chen
Executive Administrator
315 W36th St
New York, New York 10018

Re: K181929
Trade/Device Name: MiMo™ Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: February 21, 2019
Received: February 22, 2019

Dear Richard Chen:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kimberly Ferlin -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181929

Device Name
MiMo(TM) Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
The MiMo™ Negative Pressure Wound Therapy System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of low to moderate exudates and infectious material.
Appropriate wound types include:
- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

MiMo™ Negative Pressure Wound Therapy System is a single patient use device.

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."

Traditional 510K Summary
Negative Pressure Wound Therapy

Baymax Research, Inc.
315 W 36th St,
New York, NY 10018

E-mail: info@baymaxresearch.com
Tel: 646.828.7848

Contact Person: Mr. Richard Chen

Date Prepared: March 6, 2019

Name of Device

MiMo™ Negative Pressure Wound Therapy System

Common or Usual Name

Powered Suction Pump

Classification Name

OMP, Negative Pressure Wound Therapy Powered Suction Pump
21 C.F.R. § 878.4780

Predicate Device

Genadyne UNO Negative Pressure Wound Therapy System, K180840

Device Description

The MiMo™ Negative Pressure Wound Therapy System is a portable, battery powered wound suction pump with the intention to deliver negative pressure to the wound. It consists of an electric diaphragm vacuum pump and the output pressure is regulated by a pressure sensor that reads the pressure from the wound site via connecting to the dressing. The system comes with 2 sets of silicone wound dressings. When the pump is turned on, the user will have a choice to either use 75mmHg suction or 125mmHg suction. The user will also have a choice to choose either a continuous therapy or an intermittent therapy. The MiMo™ Negative Pressure Wound Therapy System is intended for use in the professional healthcare environment. The device is powered by 4 x AAA batteries that would be able to last the user over 48 hours of usage depending upon leak rate. The batteries can be replaced if required. The pump is programmed to stop working after 168 hours (7 days) of use and will not re-start after this time, even with a new set of batteries. There will be no negative pressure at this point. The MiMo™ Negative Pressure Wound Therapy System does come with a carry bag as well as a leg strap for convenience use for the patient.

Intended Use / Indications for Use

The MiMo™ Negative Pressure Wound Therapy System is indicated for use in patients who would benefit from negative pressure wound therapy, particularly as the device may promote wound healing by the removal of low to moderate exudates and infectious material.
Appropriate wound types include:
- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

The MiMo™ Negative Pressure Wound Therapy System is a single patient use device.

Technological Characteristics

Comparison between New and Predicate Device

The indication for use statement of the MiMo™ Negative Pressure Wound Therapy System is similar to the Predicate device. The difference between the New device and the predicate device are as follow:-

Comparative Information		
	Predicate Device	**New Device**
Company	Genadyne Biotechnolgies, Inc.	Baymax Research, Inc.
Device Name	Genadyne UNO Negative Pressure Wound Therapy System	MiMo™ Negative Pressure Wound Therapy System
510(k) Number	K180840	K181929
Technical Data		
Vacuum Choices	125 mmHg and 80 mmHg	125 mmHg and 75 mmHg
Max Vacuum	125 mmHg	125 mmHg
Battery Type	Alkaline Manganese Dioxide AA (QU1500)	AAA Batteries
Power (Battery)	3V DC	6V DC
Dimensions / Weight	3” x 4.4” x 2.4” / 400g	5.8” x 2.78” x 1.06” / 129g

Operating Time	7 days	7 days
Therapy Mode	Continuous and Intermittent	Continuous and Intermittent
Accessories		
Canisters	Two 70 ml disposable canister with a build-in hydrophobic shut off filter for overflow protection	Two 60 ml disposable canister with a build-in hydrophobic shut off filter for overflow protection
Reusable	No	No
Sterile	Dressings provided are sterile	Dressings provided are sterile
Accessories		
Dressings	10cm x 20cm 10cm x 30cm 10cm x 40cm 15cm x 15cm 15cm x 20cm 15cm x 30cm 20cm x 20cm 20cm x 25cm 25cm x 25cm	12.5 x 12.5 cm 12.5 x 18.75 cm 12.5 x 25 cm 12.5 x 35 cm 17.5 x 22.5 cm 17.5 x 32.5 cm 12.5 x 40 cm
	4 x Fixation Strips	4 x Fixation Strips
	Carrying Case	Carrying Case and Leg Strap
Indications for Use		
	UNO is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of low to	The MiMo™ Negative Pressure Wound Therapy System is indicated for use in patients who would benefit from negative pressure wound therapy

	moderate exudates and infectious material. Appropriate wound types include: - Chronic - Acute - Traumatic - Subacute and dehisced wounds - Partial-thickness burns - Ulcers (such as diabetic or pressure) - Flaps and grafts - Closed surgical incisions Genadyne UNO is a single patient use device.	particularly as the device may promote wound healing by the removal of low to moderate exudates and infectious material. Appropriate wound types include: - Chronic - Acute - Traumatic - Subacute and dehisced wounds - Partial-thickness burns - Ulcers (such as diabetic or pressure) - Flaps and grafts - Closed surgical incisions The MiMo™ Negative Pressure Wound Therapy System is a single patient use device.
Contraindications		
-	The UNO is contraindicated in the presence of:	MiMo™ is contraindicated in the presence of:
-	Necrotic tissue with Eschar present	Necrotic tissue with Eschar present
-	Previously confirmed and untreated osteomyelitis.	Untreated osteomyelitis
-	malignancy in the wound bed or margins of the wound (except in palliative care to enhance quality of life)	Malignancy (with exception to enhance quality of life)
-	Exposed arteries, veins, or organs	Exposed arteries, veins, or organs
-	Non-enteric and unexplored fistulas	Non-enteric and unexplored fistulas
-	Anastomotic sites	Anastomotic sites
-	Emergency airway aspiration	Emergency airway aspiration
-	Pleural, mediastinal or chest tube drainage	Pleural, mediastinal or chest tube drainage
-	Surgical suction	Surgical suction

Compliance		
	IEC 60601-1	IEC 60601-1
	IEC 60601-1-2	IEC 60601-1-2
		IEC 60601-11
		EN/ISO 62366
Storage / Transport		
	-18°C to +43°C (0°F to 110°F)	-25°C to +70°C (-13°F to 158°F)
	Relative Humidity 10% to 95 %	Relative Humidity 20% to 85 %
	700 - 1060 mbar Atmospheric pressure	700 – 1060 mbar Atmospheric pressure
Operation	18°C to 34°C (65°F to 94°F)	5°C to 40°C (41°F to 104°F)
	Relative Humidity 10% to 95 %	Relative Humidity 20% to 90 %
	700 - 1060 mbar Atmospheric pressure	700 - 1060 mbar Atmospheric pressure

Discussion of Non Clinical Tests Performed

The biocompatibility of the MiMo™ Negative Pressure Wound Therapy System dressing has been demonstrated through assessment according to ISO 10993 standards. In-vitro and in-vivo tests were done on the complete dressing set that includes the fixation strips.

Electrical safety testing was also completed in accordance to IEC 60601-1 and IEC 60601-1-2.

Bench testing was completed to show evidence that the device meets the operational requirements, including pressure maintenance and fluid removal capacity.

Conclusion & Determination of Substantial Equivalence

Based on the information presented above, the MiMo™ Negative Pressure Wound Therapy System is technologically similar to the predicate device (Genadyne UNO Negative Pressure Wound Therapy System – K180840) in terms of pressure management and therapy mode provided.

The MiMo™ Negative Pressure Wound Therapy System does not raise any new issues of safety and effectiveness.

The MiMo™ Negative Pressure Wound Therapy System is substantially equivalent to the predicate device.