May 4, 2020

BenQ Materials Corporation
Isabel Tsai
Regulatory Affairs Department
29 Jianguo E. Rd., Guishan
Taoyuan, TW 33341

Re: K193185
Trade/Device Name: Anscare SIMO Negative Pressure Wound Therapy (NPWT) System
Regulation Number: 21 CFR 878.4683
Regulation Name: Non-Powered Suction Apparatus Device Intended For Negative Pressure Wound Therapy
Regulatory Class: Class II
Product Code: OKO
Dated: January 15, 2020
Received: January 22, 2020

Dear Isabel Tsai:

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,

Kimberly M. Ferlin, Ph.D.
Acting 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)*
K193185

Device Name
Anscare SIMO Negative Pressure Wound Therapy (NPWT) System (SIMO System)

Indications for Use *(Describe)*
SIMO System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of excess exudate and infectious materials.

SIMO System is suitable for use in both hospital and homecare setting and is indicated for the following wound types:
- Chronic wounds
- Acute wounds
- Traumatic wounds
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

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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510(k) Summary

General Information:

Type of Submission:	Traditional
Submitter:	BenQ Materials Corporation
Address:	No. 29, Jianguo E. Rd., Gueishan, Taoyuan, 33341, Taiwan, R.O.C
Phone:	+886-3-374-8800
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Contact:	Isabel Tsai (Isabel.Tsai@BenQMaterials.com)
Registration number:	3010256218
Date prepared:	May 4, 2020

Identification of the Device:

Device Name:	Anscare SIMO Negative Pressure Wound Therapy (NPWT) System
Classification Name:	Non-Powered suction apparatus device intended for negative pressure wound therapy
Device Classification:	Class II
Regulation Number:	21 CFR 878.4683
Panel:	General & Plastic Surgery
Product Code:	OKO

Identification of the Predicate Device:

Predicate Device Name:	SNaP® Wound Care System
Manufacturer:	Spiracur Inc.
Classification Name:	Non-Powered suction apparatus device intended for negative pressure wound therapy
Device Classification:	Class II

Regulation Number:	21 CFR 878.4683
Panel:	General & Plastic Surgery
Product Code:	OKO
510(k) Number:	K151710
Reference Device Name:	PICO Single Use Negative Pressure Wound Therapy System
Manufacturer:	Smith & Nephew Medical Inc.
Classification Name:	Powered suction pump
Device Classification:	Class II
Regulation Number:	21 CFR 878.4780
Panel:	General & Plastic Surgery
Product Code:	OMP
510(k) Number:	K151436
Clearance Date:	January 28, 2016

Device Description

1.1 Device Identification:

Anscare SIMO Negative Pressure Wound Therapy (NPWT) System including non-sterilized SIMO Pump and sterilized SIMO Dressing. Patient is able to carry the SIMO Pump easily in the pocket or a belt holder (additional accessory). Anscare SIMO Negative Pressure Wound Therapy (NPWT) System is also called "SIMO System" in the following description.

SIMO System has 3 types of model variants including "2 SIMO Dressings and 1 SIMO Pump", "2 SIMO Dressings and 1 SIMO Pump with 1 holder" and "3 SIMO Dressings". Each type has 4 models, and each model contains 4 different sizes of SIMO dressing separately.

1.2 Device Characteristics:

SIMO System is for single person use only. SIMO Pump could use for 30 days. The SIMO Dressing is sterilized by Ethylene Oxide and single-use.

1.3 Environment of Use:

SIMO System is suitable for use both in a hospital and homecare setting.

1.4 Brief Written Description of the Device:

SIMO System including non-sterilized negative pump and sterilize dressing. The negative pressure wound therapy is provided by a pump (-125±15mmHg) up to 30 days by manual and may promote wound healing via the removal of exudate. The negative pressure is provided by the SIMO Pump, and the exudates of wound bed is managed by the dressing. SIMO Dressing is applied to the wound. It should be changed in line with standard wound management guidelines, typically every 3-4 days up to 7 days. More frequent dressing changes may be required depending on the level of exudates, condition of the dressing, wound type/size, orientation of the dressing, environmental considerations and/or other patient considerations.

Indication for use

SIMO System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of excess exudate and infectious materials.

SIMO System is suitable for use in both hospital and homecare setting and is indicated for the following wound types:

- Chronic wounds
- Acute wounds
- Traumatic wounds
- Subacute and dehisced wounds

- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

Comparison of Technological characteristics with the predicate device

SIMO System is substantially equivalent in intended use to the predicate devices: SNaP® Wound Care System (K151710).

The device is indicated for negative pressure wound therapy (NPWT) that is intended for wound management via application of continual negative pressure to the wound for removal of fluids, including wound exudate and infectious materials.

SIMO System and the predicate device (SNaP® Wound Care System) are both non-powered, negative pressure wound therapy device used for the same indicated use. Both systems utilize manually pump to generate the negative pressure gradient.

The SIMO System is canister-free. Exudate is retained in the absorbent dressing and allows fluid to evaporate. The technology is similar to the reference device: PICO Single Use Negative Pressure Wound Therapy System (K151436) which has similar absorbable NPWT dressing component, mechanism and performance compared with the subject device.

Device Comparison Table

Brand and product / Items	Anscare SIMO System	SNaP® Wound Care System	PICO Single Use Negative Pressure Wound Therapy System
FDA regulation status	K193185	K151710	K151436
Regulatory Class	Class II	Class II	Class II
Product code	OKO	OKO	OMP
Manufacturer	BenQ Materials Corp.	Spiracur Incorporated	Smith & Nephew medical Ltd.
Indications for Use	SIMO System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of excess exudate and infectious materials. SIMO System is suitable for use in both hospital and homecare setting and is indicated for the following wound types: • Chronic wounds • Acute wounds • Traumatic wounds • Subacute and dehisced wounds •Partial-thickness burns • Ulcers (such as diabetic or pressure) • Flaps and grafts • Closed surgical incisions	SNaP System with SNaP Cartridge (60cc): The SNaP® Wound Care System is indicated for patients who would benefit from wound management via the application of negative pressure, particularly as the device may promote wound healing through the removal of excess exudate, infectious material and tissue debris. The SNaP® Wound Care System is indicated for removal of small amounts of exudate from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts. SNaP System with SNaP Plus Cartridge (150cc): The SNaP® Wound Care System is	PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. 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 • PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both hospital and homecare setting.

			indicated for patients who would benefit from wound management via the application of negative pressure, particularly as the device may promote wound healing through the removal of excess exudate, infectious material and tissue debris. The SNaP® Wound Care System is indicated for removal of exudate from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.	
Technology	External use only	Yes	Yes	Yes
	Therap. Delivery Mode	Continuous	Continuous	Continuous
	Structure	Pump + tube + dressing	Pump + tube + canister + dressing	Pump + tube + dressing
	Power supply	Manual	Manual	Powered
	Max pump pressure	125 mmHg	125 mmHg	100 mmHg
	Biocompatibility	Pass	Pass	Pass

Technology	Sterilization	Ethylene Oxide	Gamma	Ethylene Oxide
	Shelf-life	3 Years	2 Years	3 Years

Performance Testing – Bench

In order to ensure Anscare SIMO Negative Pressure Wound Therapy (NPWT) System effective, we designed performance test item to description of the evaluation and the test conclusion are as below:

- Tubing Tensile Strength Test

  To conduct this test for testing the user's pull on it, the testing is for tubing tensile strength test. Based on the test results, we can see that our SIMO System is within the safe range of tube tensile strength and will not fail the treatment due to careless pulling of the user and will not cause any user safety and functional problems.

- Adhesive test

  To conduct this test for testing the product viscosity does not meet the specifications after sterilization, resulting in the user functional and safety concerns. Based on the test results, we can see that our dressing viscosity meet the specifications after sterilization, so it will not lead to user safety and functional problems.

- Function Test after Drop Testing

  To conduct this test for testing the product would not cause component failure due to the user's careless dropping, resulting in the user's safety and functional risks. According to the test results, we can see that if the user uses the device without pay attention and caused falling, it will not lead to malfunction, caused by user safety and security concerns.

- Life Time for 30 Days Test

  To conduct this test for testing the product does not cause fatigue or malfunction of the pump due to the increase in the frequency of uses, resulting in safety and functional risks to the user. According to the test results, we can see that our device has been pressed 150 times, the stable pressure output of the device does not cause malfunction due to falling, it is still normal use, does not lead to the user's safety and functionality problems.

- Simulation Test

  To conduct this test for the make sure the product could be well-operated under different circumstances of exudate, low(0.3 ml/cm^2/24h) and moderate (1.1 ml/cm^2/24h), and the ability in providing stable pressure and managing exudate. We can conclude that Anscare SIMO System can provide effective and stable negative pressure for managing exudate, such as permeability, evapotranspiration rate, and the liquid reflux rate (the ability to keep exudate in the dressing), and the performance tests are all pass. Last but not least, the Smart pattern of Anscare SIMO System is designed not only to notify patients about the condition of negative pressure wound therapy, but to avoid patients failing to judge the changing timing of the dressing, making it more effective and efficient in wound healing.

- HFE/UE Report

  Anscare SIMO NPWT system has been found to be safety and effective for the intended users (healthcare professional, a caregiver or patient) uses and use environments. 15 HCPs and 15 lay users were recruits for the validation testing with the different tasks and use scenario.

  The conclusion was supported by the HFE/UE processes which complied with "Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff (2016)" and analysis of the results.

Biocompatibility and Sterilization Testing

SIMO dressing is the patient direct contacting component of the SIMO System. Further, in the choice of our materials, SIMO Dressing was similar to the predicate device, it was only different from two additional layers. To prove there is no additional safety concern, the biocompatibility evaluation for the SIMO Dressing was conducted in accordance with ISO-10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'. Appropriate tests had been conducted using final product that has been packaged and sterilized. The testing included the following tests:

- In Vitro Cytotoxicity Test
- Skin Sensitization Test
- Intracutanous Skin irritation Study
- Acute Intravenous Systemic Toxicity Study
- Acute Intraperitoneal Systemic Toxicity Study
- Pyrogen Test
- Subacute/subchronic toxicity study
- Implantation study
- Phthalate leachables study

From the results and analysis above, it shows that the SIMO system passed the evaluated biocompatibility tests.

Additional, SIMO Dressing is the part of SIMO System which will come in to direct contact with the wounds and normal skin of patients. Concerning the risk of the microbial infection, we conduct the EO sterilization to the SIMO Dressing. To make sure the sterile conditions and sterilization process, we conducted the sterilization valuation in accordance with ISO 11135, 'Sterilization of health-care products — Ethylene oxide — Requirement for the development, validation and routine control of a sterilization process for medical devices'. The residual testing had been performed in accordance with ISO 10993-7 which confirm the SIMO Dressing comply with the allowable residual limits for ethylene oxide (EO)

and its reaction products.

Conclusion

Anscare SIMO Negative Pressure Wound Therapy (NPWT) System has similar indications for use and technological characteristics to the predicate device. The non-clinical data, biocompatibility test, sterilization test demonstrates the substantial equivalence of the SIMO System to the SNaP® Wound Care System (K151710).