August 23, 2019

ACARE Technology Co., Ltd.
% Ming-Yie Jan
RusCert Technology Co., Ltd.
8F.-2, No.21, Sec. 6, Zhongxiao E. Rd., Nangang Dist.
Taipei City, Taiwan

Re: K182950
Trade/Device Name: Acare Suction Unit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: JCX
Dated: July 26, 2019
Received: July 29, 2019

Dear Ming-Yie Jan:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# SECTION 4 INDICATIONS FOR USE STATEMENT

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)*
K182950

Device Name
Acare Suction Unit, model ASU-200

Indications for Use *(Describe)*
The device is to be used to remove fluids from the airway or respiratory system. The device creates a negative pressure (vacuum) that draws fluids through disposable tubing that is connected to a collection canister. The fluids are trapped in the collection canister for proper disposal. It is for use on the order of a physician only.

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.

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# ACARE TECHNOLOGY CO., LTD.

## 510 (K) Summary

### 5.1 Submitter's Information


| | |
|---|---|
| Name: | ACARE TECHNOLOGY CO., LTD. |
| Address: | 5f-4, No.24, Wuquan 2nd Rd., Xinzhuang Dist., New Taipei City 242, Taiwan |
| Establishment Registration Number: | 3006395447 |
| Contact: | Kevin Tsai / QA manager<br><br>Tel: + 886-2-2298-8170 #204<br>Fax: +886-2-22988560<br>E-mail: Kevin@acarecorp.com<br><br>Or<br><br>Linda Cheng / General Manager |


| | |
|---|---|
| Date Prepared: | September 30, 2018 |

### 2. Device Name

| | |
|---|---|
| Trade Name: | Acare Suction Unit, model ASU-200 |
| Common/usual Name: | Acare Suction Unit, model ASU-200 |
| Device Classification Names: | Apparatus, Suction, Ward use, Portable, Ac-Powered |
| Panel: | General & Plastic Surgery, |
| Product Code: | JCX |
| Classification: | Class II |
| Regulation Description: | Powered Suction Pump |
| Regulation Number: | §878.4780 |

### 5.3 Predicate Devices:

(a) VacPlus Suction Unit, 510(k) Number: K103535

(b) EMG Suction Unit, 510(k) Number: K112421

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## 5.4 Indication for Use

The device is to be used to remove fluids from the airway or respiratory system. The device creates a negative pressure (vacuum) that draws fluids through disposable tubing that is connected to a collection canister. The fluids are trapped in the collection canister for proper disposal. It is for use on the order of a physician only.

## 5.5 Device Description

The Acare Suction Unit, model ASU-200 is to be used to remove fluids from the airway or respiratory system. The device creates a negative pressure (vacuum) that draws fluids through disposable tubing that is connected to a collection canister. The fluids are trapped in the collection canister for proper disposal. The device is a rugged, compact and portable electrically-operated medical suction device, designed for multi-source powering from AC (External 100V– 240 V) or DC (External 12V DC) mains supply or internal rechargeable battery, and is ideally suited for field, transport and hospital/clinical use applications.

The Acare canister is an accessory to the Acare Pump and the removed body fluids are collected in it. The Acare Pump is an AC powered oil-less positive displacement pump capable of delivering up to 600 mmHg of vacuum to draw fluid and small particles. The Acare Pump has a plastic casing fitted with a power (ON/OFF) button, power indicator, one suction adjustment knob, a suction gauge and a canister holder. The Acare canister is a preassembled 1000 mL canister including canister tubing fitted with a microbial filter at the distal end. The canister is fitted with a removable lid for fluid containment and an overflow protection device. The Acare canister should be placed in the in-built canister holder and connect the Acare canister with the Acare Pump via the connectors of the canister tubing prior to use.

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## 5.6 Comparison of Technological Characteristics

A summary of the technological characteristics of the device subject of this premarket notification in comparison to those of the predicate devices is included in **Table 5-1.**

**Table 5-1.** Summary of the Proposed and Predicate Devices Technological Characteristics

| Feature | Proposed device | Predicate device (a) | Predicate device (b) | Comparison |
|---|---|---|---|---|
| **Device** | **Acare Suction Unit, model ASU-200 (K182950)** | **VacPlus Suction Unit (K103535)** | **EMG Suction Unit (K112421)** | |
| **Classification Name** | Apparatus, Suction, Ward use, Portable, Ac-Powered | Apparatus, Suction, Ward use, Portable, Ac-Powered | Apparatus, Suction, Ward use, Portable, Ac-Powered | Same |
| **Classification / Product Code** | Class II / JCX | Class II / JCX | Class II / JCX | Same |
| **Indication for Use** | The device is to be used to remove fluids from the airway or respiratory system. The device creates a negative pressure (vacuum) that draws fluids through disposable tubing that is connected to a collection canister. The fluids are trapped in the collection canister for proper disposal. It is for use on the order of a physician only. | The device is to be used to remove fluids from the treated Tracheotomy patient airway. | The device is to be used to remove body fluids from a patient's airway or respiratory system. It is for use on the order of a physician only. | Similarity |
| **Product Type** | AC-Powered suction pump | AC-Powered suction pump | AC-Powered suction pump | Same |
| **Electrical requirement** | AC 100-240V, 50/60Hz DC 18V | AC 110-240V, 50/60Hz DC 12V | AC 100-240V, 47-63Hz, DC14V, | Similarity |
| **Power Consumption** | 35 VA | 40W | 38W | Similarity |
| **Battery** | Li-ion Battery: 14.8Vdc, 2.5Ah | Lead Acid battery, 12Vdc, 2.8Ah | Li-ion Battery: 12Vdc, 2.5Ah | Similarity |
| **Indication of Vacuum Level** | Analogue Vacuum Gauge/ 760mmHg/100kPa | Analogue Vacuum Gauge/ 760mmHg/100kPa | Analogue Vacuum Gauge 76cmHg/30inHg | Same |
| **Maximum Vacuum (Pressure)** | 600 mmHg | 600 mmHg | 600 mmHg | Same |
| **Maximum Flow Rate** | 24 LPM | 24 LPM | 20~25LPM | Same |
| **Sound Level (Noise level)** | Pass ISO 10079-1 | Pass ISO 10079-1 | Pass ISO 10079-1 | Same |

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**Table 5-2.** (Continued) Summary of the Proposed and Predicate Devices Technological Characteristics

| Feature | Proposed device | Predicate device (a) | Predicate device (b) | Comparison |
|---|---|---|---|---|
| **Device** | **Acare Suction Unit, model ASU-200 (K182950)** | **VacPlus Suction Unit (K103535)** | **EMG Suction Unit (K112421)** | |
| **Type of Pump** | Oil-less Piston pump | Oil-less Piston pump | Oil-less Piston pump | Same |
| **Pressure Control** | adjusted by tuning the knob of vacuum adjusting set | adjusted by tuning the knob of vacuum adjusting set | adjusted by tuning the knob of vacuum adjusting set | Same |
| **Disposable Canister** | Yes | Yes | Yes | Same |
| **Connection tube** | Yes | Yes | Yes | Same |
| **Patient Tube** | Yes | Yes | Yes | Same |
| **Overflow protection** | Yes | Yes | Yes | Same |
| **Bacterial filter** | Yes | Yes | Yes | Same |
| **Operating Environment** | Temp: 50˚F~104˚F (10˚C ~40˚C)<br>Humidity:10%-90% RH | Temp: 50˚F~104˚F (10˚C ~40˚C)<br>Humidity:10%-90% RH | Temp: 32°F~104°F (0°~40 °C)<br>Humidity:< 95%RH | Similarity |
| **Operating Atmospheric** | 700~1060hPa | 700~1013hPa | 700~1060hPa | Similarity |
| **Storage Environment** | Temp: 59˚F~122˚F (15˚C ~50˚C)<br>Humidity:10%～ 90% RH | Temp: -15°C to 50°C (+5°F to +122°F)<br>Humidity:10%～ 90% RH | Temp: 14°F~158°F (-10°C~70 °C)<br>Humidity: < 95% RH | Similarity |
| **Dimensions** | 19.0cm×11.0cm×17.5cm | 35.2cm×20.6cm×19.2cm | 38.0cm×25.0cm×26.0cm | Similarity |
| **Weight** | 1.7 kg | 3.3 kg | 2.6 kg | Similarity |

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**Table 5-2.** (Continued) Summary of the Proposed and Predicate Devices Technological Characteristics

| **Feature** | **Proposed device** | **Predicate device (a)** | **Predicate device (b)** | **Comparison** |
|---|---|---|---|---|
| **Performance Testing** | **Acare Suction Unit, model ASU-200 (K182950)** | **VacPlus Suction Unit (K103535)** | **EMG Suction Unit (K112421)** | |
| **Electromagnetic compatibility (EMC)** *IEC 60601-1-2* | Passed | Passed | Passed | Same |
| **Basic safety and Essential performance** *IEC 60601-1 (ANSI/AAMI ES 60601-1)* | Passed | Passed | Passed | Same |
| **Electrically powered suction equipment - Safety requirements** *ISO 10079-1* | Passed | Passed | Passed | Same |
| **Degrees of protection provided by enclosures (IP Code)** *IEC 60529* | IP 21 | IP 21 | IP 21 | Same |

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**5.7 Summary of Non-Clinical Testing**

The Acare Suction Unit, model ASU-200 has the identical intended use and indication for use as the predicate devices. The subject device was compared to the predicate device by testing the electrical specifications, vacuum range, flow rate, power options, and operation environment.

The results of the Acare Suction Unit, model ASU-200 validation studies demonstrate that the Suction Unit perform as intended. The results are summarized as follows:

- The electromagnetic compatibility (EMC) testing performed as described in IEC 60601-1-2 Edition 3: 2007-03, "Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests". The results confirm that the testing results demonstrate of the Acare Suction Unit, model ASU-200 met the electromagnetic compatibility (EMC) encompasses both emissions (interference with electronic products) and immunity (interference with device performance created by emissions from other electronic products).
- The protection against electrical hazards from equipment, Protection against excessive temperates and other hazards, hazards situations and fault conditions, construction of equipment and electromagnetic compatibility of equipment and systems, etc. testing performed as described in ANSI/AAMI ES 60601-1:2005/(R)2012 and C1:2009/(R)2012, "Medical electrical equipment – Part 1: General requirements for basic safety and essential performance". The testing results demonstrate of the Acare Suction Unit, model ASU-200 met safety and essential performance testing acceptance criteria for each test mentioned above.
- The Needle Flame Test, Measurement of the patient leakage current, Measurement of the vibration and noise of equipment other than the low vacuum equipment, Liquid overflow/ spillage test, Air Leakage test, Interruption of the power supply, Abnormal operation and fault conditions, Environmental tests for equipment for field and/or transport use, Degree of collapse test, Airflow and Vacuum tests, and Resistance to implosion, etc. testing performed as described in ISO 10079-1:2009, "Medical suction equipment Part 1: Electrically powered suction equipment — Safety requirements". The testing results demonstrate of the Acare Suction Unit, model ASU-200 met Safety requirements testing acceptance criteria for each test mentioned above.
- The classification of degrees of protection provided by enclosures for electrical equipment testing performed as described in IEC 60529-2013, "Degrees of protection provided by enclosures (IP Code)". The testing results demonstrate of the Acare Suction Unit, model ASU-200 met IP 21 testing acceptance criteria for each test mentioned above.

**8. CONCLUSION**

The conclusions drawn from the-nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as the predicate device K103535 and K112421.