K130001

JUL 25 2013

510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92

1.0 Submitter's Information

Establishment Registration Name:

Foshan Care Medical Technology Co., Ltd.

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Contact Person of applicant
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Contact Person of the Submission:

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Foshan Care Medical Technology Co., Ltd.

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2.0 Device Information

Type of 510(k) submission:	Traditional
Device Common Name:	Power Suction Unit
Trade Name:	Model SU01A Suction aspirator
Model:	SU01A
Classification name:	Apparatus, Suction, Ward Use, Portable, AC-Powered
Review Panel:	General & Plastic Surgery

CARE Suction aspirator-510(K):Sec.5

Product Code:	JCX
Regulation Class:	II
Regulation Number:	878.4780

3.0 Predicate Device Information

Sponsor:	EMG Technology Company, Ltd
Device:	Suction Unit, Model:SUA01
510(K) Number:	K042349
Product Code:	JCX
Regulation Class:	II
Regulation Number:	878.4780

4.0 Device description

Powered suction pumps are described in FDA regulations, 21 CFR 878.4780, as:

"A powered suction pump is an AC-powered device intended to be used to remove infectious materials from wounds or fluids from patient's airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter. The FDA classified the device as a class II medical device".

The SU01A Suction aspirator is designed to provide general suction for use in hospitals or clinics. This Suction aspirator is a professional medical suctioning device that produces a maximum vacuum of 560 mmHg. It is used with a power supply allowing operation on AC voltage (120 VAC, 60 Hz). The device is equipped with 850ml collection bottle and has been designed for convenient and reliable and reliable usages.
The vacuum pump of the SU01A transmits negative pressure throughout the tubing-system and the collection bottle to patient tubing that aspirates secretions or liquid form the body. The vacuum pump can be manually adjusted using the regulating value and the vacuum gage. The aspirated fluids are collected in the collection bottle that is isolated from the pump by a bacteria filter. It also has a mechanical overflow protection in the lid of the collection bottle to further prevent the fluids from being sucked into the pump.

5.0 Intended Use

The CARE SU01A Suction aspirator is intended for professional use to remove infectious materials from wounds or fluids from a patient airway or respiratory support unit. The intended large population for this device is both adult and pediatric patients.

6.0 Determination of Substantial Equivalence

Summary of Technological Characteristics of the Device Compared to the Predicate Device

The CARE SU01A Suction aspirator uses the same fundamental technology as the EMG SUA01 Suction Unit for most features. The indications for use of CARE SU01A Suction aspirator are the same as EMG SUA01 Suction Unit. CARE SU01A Suction aspirator is similar to the predicate devices in its indications for use and patient population. The user interface is also similar to the predicated devices. The main difference is in the volume of the collection bottle, which is increased but still sufficient for the expected daily volumes. The smaller size improves mobility.

Summary of Non-clinical Tests:

The CARE SU01A Suction aspirator complies with voluntary standards for electrical safety, electromagnetic compatibility, and performance. The following quality assurance measures were applied to the development of the system:

- Electrical safety and electromagnetic compatibility testing per IEC 60601-1 and IEC 60601-1-2 standards, respectively
- Medical suction equipment - Part 1: Electrically powered suction equipment - Safety requirements per ISO 10079-1

Summary of Clinical Tests:

No clinical studies were performed

CONCLUSION:

Foshan Care considers the SU01A Suction aspirator to be as safe, as effective, and substantially equivalent to the predicate devices.

7.0 Effectiveness and Safety Considerations

Effectiveness:
The SU01A Suction aspirator complies with ISO10079-1:1999.

Safety Considerations:

The applicant devices comply with IEC60601-1, Medical electrical equipment - Part 1: General requirements for safety and IEC60601-1-2, Medical electrical equipment - Part 1-2: General requirements for safety -Collateral standard: Electromagnetic compatibility - Requirements and tests.

The SU01A Suction aspirator is not a software controlled medical device, the software test according the software guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" is not applicable.

The accessories which contact the patients directly are provided by the hospital but not the manufacture. All the accessories of the SU01A Suction aspirator are not contact the patients, the biocompatibility test is not applicable.

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The clinical performance test is not applicable

8.0 Comparison to predicate device and conclusion

Comparison Analysis

The applicant device has same classification information, same indications and intended use, similar product design, similar technical specification and safety specification.

Attribute	SU01A Suction Pump	SUA01 Suction Unit	Results
The pump shall be compliant with IEC 60601-1 requirements	Meet the requirements	Meet the requirements	Pass
The pump shall be compliant with IEC 60601-1-2 requirements	Meet the requirements	Meet the requirements	Pass
The pump shall be compliant with ISO 10079-1 requirements	Meet the requirements	Meet the requirements	Pass
The pump controls shall be easily identifiable by user	Meet the requirements	Meet the requirements	Pass
The Collection Bottle should have volume reference markings	850ml	800ml	Pass
The Collection Bottle should be able to withstand maximum pressure delivered by the pump	Meet the requirements	Meet the requirements	Pass
The degree of collapse of the tubing shall be less than 0,5 throughout its entire length when subjected to the maximum vacuum stated	Less than 0,5	Less than 0,5	Pass
The resistance to implosion for collection container	Meet the requirements	Meet the requirements	Pass
The flow rate of maximum pumping power	Meet the requirements	Meet the requirements	Pass

Conclusion:
The applicant device is **Substantially Equivalent** (SE) to the predicate device which is US legally marketed device. Therefore, the applicant device is determined as safe and effectiveness.

Compare with predicate device, they are very similar in design principle, intended use, functions, material and the adopting applicable standards. The differences between applicant device and predicate device do not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

July 25, 2013

Foshan Care Medical Technology Co., Ltd.
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K130001
Trade/Device Name: Care SU01A Suction Aspirator
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: JCX
Dated: July 16, 2013
Received: July 17, 2013

Dear Mr. Job:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

FOR Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K130001
Device Name: Suction aspirator
Model: SU01A

Indications for Use:

The CARE SU01A Suction aspirator is intended for professional use to remove infectious materials from wounds or fluids from a patient airway or respiratory support unit. The intended large population for this device is both adult and pediatric patients.

Prescription Use__X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DSD—Division Sign-Off	
Division of Surgical Devices	Joshua C. Nipper -S
510(k) Number: K130001	