510K Summary

510(K) SUMMARY

Submitter:

Devon Medical Inc.

Contact Person:

Ruth Wu, COO
1100 First Avenue, Suite 202
King of Prussia, PA 19406
Phone: 866.446.0092
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Common Classification & Proprietary Names:

Common Names: Negative Pressure Wound Therapy System
Proprietary Names: extriCARE 3600
extriCARE Foam Kit

Date Prepared:

January 16th, 2013

Classification

The classification name, 21 CFR Part and Paragraph number, product code and classification of the extriCARE 3600:

FDA	Classification	Product Code	Class
21 CFR 878.4780	Powered Suction Pump	OMP	II

Predicate Devices:

The extriCARE 3600 Negative Pressure Wound Therapy System and extriCARE Foam Kit is substantially equivalent to the following:

Predicate Device	Manufacturer	510(k)#
extriCARE 2400	Devon Medical	K110078
V.A.C.® Freedom™	Kinetic Concepts, Inc.	K032310
Wound Pro Apex	Accuro Medical Products LLC	K100823
NPWT Foam Dressing Kits	Smith & Nephew	K082211

Device Description

The system consists of a vacuum pump, canister, tubing, NPWT bandage or NPWT Foam Kits. In operation, the device is attached via the tubing to a

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Negative Pressure Wound bandage or foam kits. Maximum pressure and continuous mode or intermittent mode selection are digitally programmable. The extriCARE 3600 pump can be sold alone or as a part of the extriCARE 3600 system with extriCARE bandages or foam kits. The extriCARE bandages are an all-in-one wound dressing; with no wound packing required which is cleared in the predicate K110078. The foam kit consists of Polyurethane foam, transparent film drape, paper ruler, Suction Bell with connecting (drainage) tube and clamp, which is included in this submission for review.

Intended Use:

The extriCARE 3600 Negative Pressure Wound Therapy 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 extriCARE 3600 Negative Pressure Wound Therapy 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.

Technological Characteristics:

The manufacturer believes that the technological characteristic of the extriCARE 3600 are substantially similar to those of the predicate devices. The extriCARE 3600 has very similar components to its predicate devices and very similar principles of operation. The device consists of an electrically generated source of vacuum and a canister. Like the predicates, vacuum, is applied for a specified period of time and intensity, according to the physician's prescription.

Both extriCARE bandages and foam dressing kits are alternatively used together with the extriCARE 3600 pumps. The extriCARE bandages are the same as stated in the previously cleared submission K110078.

The extriCARE foam kits 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, which may provide negative pressure to the wound site which may promote healing by removing wound exudates.

Performance Testing

To ensure the performance of extriCARE® 3600 device meet the design input when conjunction with NPWT bandage and foam kits, a series of bench tests were conducted to ensure device's functions, which include the sensors, hook, canister, clamp, air filter and a simulated wound performance test.

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EMC Testing

To verify that the device design met it's functional and performance requirements, representative samples of the device underwent function and mechanical testing, EMC testing in accordance with IEC 60601-1:2005, IEC 60601-1-2:2007 and electrical safety testing in accordance with AAMI ES 60601-1:2005 standards.

Biocompatibility

The extriCARE 3600 system consists of the pump, bandages or alternative foam kits. While the pump has no direct body contact when used as indicated, the bandage and foam kits do have direct body contact. Per ISO-10993 requirements, the bandage samples and foam kits samples were tested for the following items and all tests were successfully passed.

- In-vitro Cytotoxicity
- Skin irritation
- Skin Sensitization

Statement of Substantial Equivalence

The extriCARE 3600 system is substantially equivalent in technology, function, operating parameters, and intended use to predicate devices that are 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, Devon Medical Products, believes that the extriCARE 3600 system (pump, bandage, foam, and accessories) is safe and effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 15, 2014

Devin Medical, Inc.
Ruth Wu, Chief Operating Officer
1100 First Avenue, Suite 202
King of Prussia, Pennsylvania 19406

Re: K132225
Trade/Device Name: extriCARE® 3600 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 11, 2014
Received: February 14, 2014

Dear Ms. 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. 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

David Krause -S

for Binita Ashar, MD, MBA, FACS
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

cc: DMC
510(k) Staff
Division
D.O.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132225

Device Name
extriCARE 3600 Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
The extriCARE® 3600 Negative Pressure Wound Therapy 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 extriCARE® 3600 Negative Pressure Wound Therapy 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Jiyoung Dang -S

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