October 23, 2020

Pensar Medical, LLC
% Pierre Bounaud
Senior Regulatory specialist
AcKnowledge Regulatory Strategies, LLC
2251 San Diego Ave, Suite B-257
San Diego, California 92110

Re: K200223
Trade/Device Name: PocketDoc™ Micro Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: January 24, 2020
Received: January 29, 2020

Dear Pierre Bounaud:

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.
Assistant Director (Acting)
DHT4B: 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

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)*
K200223

Device Name
PocketDoc™ Micro Wound Therapy System

Indications for Use *(Describe)*
PocketDoc Micro Wound Therapy System is indicated for patients who may benefit from a suction device as it may promote wound healing through the removal of low to moderate levels of exudate 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

PocketDoc Micro Wound Therapy System is suitable for use in both a healthcare and homecare setting.

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
K200223

DATE PREPARED
October 23, 2020

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DEVICE INFORMATION

Proprietary Name/Trade Name:	PocketDoc™ Micro Wound Therapy System
Common Name:	Negative Pressure Wound Therapy Powered Suction Pump
Regulation Number:	21 CFR 878.4780
Class:	II
Product Code:	OMP
Premarket Review:	General & Plastic Surgery
Review Panel:	OPEQ/OHT4/Infection Control and Plastic Surgery Devices (DHT4B)

PREDICATE DEVICE IDENTIFICATION
The PocketDoc is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K151436	PICO Single Use Negative Pressure Wound Therapy System / Smith & Nephew Medical Inc.	✓

The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION
The PocketDoc™ Micro Wound Therapy System (PocketDoc) is a negative pressure wound therapy (NPWT) system that is specifically designed for shallow wounds with low to moderate amounts of exudate (~10 ml/day) that no longer or never required a collection canister. The system consists of a disposable, small, lightweight, battery operated, portable suction device (pump control unit) containing an electric motor driven vacuum pump, Enluxtra Humifiber Wound Dressings made of a hydrophilic gelling fiber (K122297), adhesive polyurethane drapes and StingRay TPE flanges with PVC tubing to connect the dressing/drape to the suction device.

The dressing is applied over the wound and the drape is applied over the dressing to hold it in place. The flange on top of the drape is connected to the pump control unit via the tubing. The dressings, drapes, flanges and tubing are supplied sterile and are for single use. The pump control unit is for single patient use and is provided nonsterile. The PocketDoc™ Micro Wound Therapy System is suitable for use in both a healthcare and homecare setting. The portable suction device can be placed in a pocket, a carrier or attached to the body with an arm/leg Velcro strap which is provided.

INDICATIONS FOR USE

PocketDoc Micro Wound Therapy System is indicated for patients who may benefit from a suction device as it may promote wound healing through the removal of low to moderate levels of exudate 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

PocketDoc Micro Wound Therapy System is suitable for use in both a healthcare and homecare setting.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Pensar Medical believes that the PocketDoc™ Micro Wound Therapy System (PocketDoc) is substantially equivalent to the predicate device based on the information summarized here:

The subject device has a similar design and dimensions and uses similar materials (plastic body, thermoplastic flange, PVC tubing, highly adsorbent dressing) as the device cleared in K151436. The subject device has the same intended use and similar technological characteristics (powered suction pump for negative pressure wound therapy) to the device cleared in K151436.

The technological differences of the PocketDoc™ Micro Wound Therapy System, when compared to the predicate device cleared in K151436, are that the subject device includes two additional set pressures (-50 and -125 mmHg), uses non-replaceable AAA alkaline batteries instead of replaceable AA lithium batteries, includes a smaller dressing size (4”x4” instead of 4”x8”), incorporates a different wound kit fixation method (film drape instead of fixation strips), and involves a different sterilization method (gamma radiation instead of ethylene oxide).

The PocketDoc has undergone testing to ensure the differences in technological characteristics do not raise different questions of safety and effectiveness compared to the predicate device.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the PocketDoc™ Micro Wound Therapy System (PocketDoc). The following tests were performed to demonstrate safety based on current industry standards:

- Sterilization validation per ISO 11137-1, ISO 11137-2, and AAMI TIR33
- Packaging and shelf life validations
- Biocompatibility per ISO 10993-1 (for a device having prolonged contact duration with breached or compromised skin)
- Software validation per IEC 62304
- Electrical safety per ANSI/AAMI ES60601-1
- Electromagnetic compatibility per IEC 60601-1-2
- Performance bench testing
    - Pressure accuracy test: Evaluate the ability of the device to administer accurate pressure in side-by-side testing with the predicate.
    - Low pressure indicator test: Evaluate the ability of the device to detect a low pressure condition in the system and engage a low pressure indicator in side-by-side testing with the predicate.
    - 96-hour exudate test: Demonstrate the ability of the device to collect exudate in the dressing during a worst-case simulated clinical scenario in side-by-side testing with the predicate.
    - Effect of PocketDoc on Enluxtra Humifiber Wound Dressing fluid management performance: Evaluate the effect of the device on the dressing fluid management performance, specifically, fluid capacity under a simulated worst-case clinical scenario.
    - Battery test: Evaluate the ability of the device to function for at least 168 hours and to engage the low battery indicators.
    - Negative pressure safety limit test: Evaluate the ability of the device to not go above the upper boundary pressure values in the event of a failure of the device in side-by-side testing with the predicate.
- Human factor studies with two groups (healthcare professionals, lay users)

The results of these tests indicate that the PocketDoc™ Micro Wound Therapy System is substantially equivalent to the predicate device.

CONCLUSION

Based on the testing performed, including sterilization validation, packaging validation, shelf life validation, biocompatibility, software validation, electrical safety, electromagnetic compatibility, performance bench testing, and human factor studies, it can be concluded that the subject device does not raise different questions of safety or effectiveness compared to the predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed PocketDoc™ Micro Wound Therapy System are assessed to be substantially equivalent to the predicate device.