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

December 1, 2016

Pensar Medical, LLC
% Elaine Duncan, Ms.ME, RAC
President
Paladin Medical, Inc.
PO Box 560
Stillwater, Minnesota 55082

Re: K150960
Trade/Device Name: WoundPro Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: October 28, 2016
Received: October 31, 2016

Dear Ms. Duncan:

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 S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K150960

Device Name
PENSAR WoundPro Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
The WoundPro Negative Pressure Wound Therapy System may promote wound healing, through the drainage and removal of infectious material and other fluids from the wound site, with continuous and/or, intermittent negative pressure. Patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts may benefit from the use of this device. The WoundPro is intended for use in a healthcare facility only.

Additional Wounds Indicated are:
· Diabetic/Neuropathic ulcers
· Pressure ulcers
· Chronic wounds
· Acute wounds
· Dehisced wounds

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)*

510(K) SUMMARY

SUBMITTER:

Submitted on behalf of:

Company Name:	Pensar Medical LLC
Address:	42225 Remington Rd, Unit A3 Temecula, CA 92590
Telephone:	(800) 669-4757
Fax:	NA
by:	Elaine Duncan, M.S.M.E., RAC President, Paladin Medical, Inc. PO Box 560 Stillwater, MN 55082
Telephone:	715-549-6035
Fax:	715-549-5380

CONTACT PERSON: Elaine Duncan

DATE PREPARED: December 1, 2016

TRADE NAME: Pensar WoundPro Negative Pressure Wound Therapy System

COMMON NAME: Negative Pressure Wound Therapy System

CLASSIFICATION NAME: Negative Pressure Wound Therapy Suction Pump (and components)

PRO CODE: OMP (Class II, 21 CFR 878.4780)

SUBSTANTIALLY EQUIVALENT TO:

PREDICATE: WoundPro Apex Negative Pressure Wound Therapy Suction Pump, Accuro Medical Products, LLC –K100823 and also features of Medela INVIA Liberty K080357

DESCRIPTION of the DEVICE:

The WoundPro is part of a family of products offered by Pensar Medical LLC. The WoundPro is a powered suction pump that uses controlled negative pressure to a dressing and flange assembly through tubing.

The control unit incorporates a maintenance free brushless DC motor and is powered by a rechargeable battery power source. Optionally the unit can be connected to mains power using the included Medical Grade Switching power converter. The device is monitored by software and contains an alarm function with audio and visual prompts.

The WoundPro has a negative pressure setting range of 20mm to 200mmHg which is electronically monitored and controlled. The pump includes push button user interface controls and an electronic display with audible and visual alarm indicators.

The device can accommodate 300cc and 800cc canister sizes.

The unit can be operated on a countertop and has provisions for connection to IV poles, bedside rails, or footboard mounting.

510(K) Submission:

INDICATIONS FOR USE:

The WoundPro Negative Pressure Wound Therapy System may promote wound healing, through the drainage and removal of infectious material and other fluids from the wound site, with continuous and/or, intermittent negative pressure. Patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps, grafts may benefit from the use of this device. The WoundPro is intended for use in a healthcare facility only.

Additional Wounds Indicated are:

- Diabetic/Neuropathic ulcers
- Pressure ulcers
- Chronic wounds
- Acute wounds
- Dehisced wounds

SUMMARY OF THE TECHNICAL CHARACTERISTICS OF THE DEVICE COMPARED TO PREDICATE

The primary predicate is the Accuro APEX WoundPro K100823 with the same indication for use and intended use.

	PREDICATE Accuro APEX WoundPro K100823	SUBJECT Pensar Medical WoundPro	SIMILARITY or DIFFERENCE
Manufacturer	Accuro (acquired by Pensar)	Pensar Medical	Pensar acquired stock and refurbished units
Product Type	Negative Pressure Wound Therapy System	Negative Pressure Wound Therapy System	SAME
Product Code	OMP (Class 2, 21 CFR 878.4780)	OMP (Class 2, 21 CFR 878.4780)	SAME
Indication For Use	The WoundPro Negative Pressure Wound Therapy System may promote wound healing, through the drainage and removal of infectious material and other fluids from the wound site. The WoundPro can provide continuous, intermittent and variable intermittent negative pressure therapies to achieve this goal. Patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts may benefit from the use of this device. At no time should the WoundPro, or any NPWT device, be used without an order from a physician. Types of Wounds Indicated are: · Diabetic/Neuropathic ulcers · Pressure ulcers · Chronic wounds · Acute wounds · Dehisced wounds	The WoundPro Negative Pressure Wound Therapy System may promote wound healing, through the drainage and removal of infectious material and other fluids from the wound site, with continuous and/or, intermittent negative pressure. Patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps, grafts may benefit from the use of this device. The WoundPro is intended for use in a healthcare facility only. Additional Wounds Indicated are: • Diabetic/Neuropathic ulcers • Pressure ulcers • Chronic wounds • Acute wounds • Dehisced wounds	SAME except for minor editorial difference
Therapy Unit	Software controlled pump for delivery of negative pressure wound therapy	Software controlled pump for delivery of negative pressure wound therapy	SAME

510(k) Summary-Continued

	PREDICATE Accuro APEX WoundPro K100823	SUBJECT Pensar Medical WoundPro	SIMILARITY or DIFFERENCE
Housing	Injection molded plastic	Injection molded plastic	SAME
Modes	Continuous or Intermittent Modes	Continuous or Intermittent Modes	SAME
Vacuum Range	20-150 mgHg	20-200mg Hg	Same as Medela, see chart below
Weight (control unit)	3.8 lbs (1.7kg)	3.8 lbs (1.7kg)	SAME
Dimensions	6.75 x 8.5 x 3.5 in (17 x 21 x 9 cm)	6.75 x 8.5 x 3.5 in (17 x 21 x 9 cm)	SAME
External Power Supply	Input: 90-264VAC, 0.8-0.4A, 47-63Hz ;Output:18VDC 1.67A	Input: 90-264VAC, 0.8-0.4A, 47-63Hz ;Output:18VDC 1.67A	SAME
Electrical Battery Powered	18VDC 25 Watts	18VDC 25 Watts	SAME
Power Source	Lithium Ion Battery or AC	Lithium Ion Battery or AC	SAME
Expected Useful Life	3 years	3 years	SAME
Collection Canisters	300 c and 800c	300 c and 800c	SAME
Filter	Hydrophobic overflow protection/bacterial filter integrated into the single-use collection canister	Hydrophobic overflow protection/bacterial filter integrated into the single-use collection canister	SAME
Dressing System	Gauze dressing with polyurethane drape.	Gauze and foam dressing with polyurethane drape.	SAME
Gauze Dressing Kit Assembly	Off the shelf components purchased sterilized.	Off the shelf components purchased sterilized.	SAME
Drape	Polyurethane with adhesive	Polyurethane with adhesive	SAME
Dome/exudates line assembly	Flange and Tubing	Flange and Tubing	SAME
Method of Sterilization	(gauze dressing purchased sterile)	gamma sterilization black foam kit	Qualified by vendor; documented in submission
Single-Use Disposable Packaging for Dressings	Single-use in Tyvek pouch	Single-use in Tyvek pouch	SAME
Biocompatibility	ISO10993-1	ISO10993-1	SAME
Accessories	EX clamp system for head/footboard or I.V. pole -WoundPro Carrying Case	EX clamp system for head/footboard or I.V. pole -WoundPro Carrying Case	SAME

The Pensar WOUNDPRO is also compared to the Medela predicate for pressure range only.

PERFORMANCE PARAMETER	MEDELA INVIA Liberty K080357	WOUNDPRO PENSAR-subject of this 510(k)	DIFFERENCE/ impact of difference
weight	<2.2 lbs	3.8lbs (1.7kg)	Pensar a bit heavier
dimensions	3.74” x 6.69 “x5.91 “	6 ¾” (w) x 8 ½” (h) x 3 ½” (d) (17 x 21 x 9 cm)	Pensar is similar in size
Power source	Lithium Ion Battery AC Power	Lithium Ion Battery AC Power	No difference
Electrical voltage	110-240V AC 47-63 Hz	90-260V AC 47-63Hz	No difference
Electrical amperage	0.8-4A	.8-.4A	No difference
Housing	Injection Molded Plastic	Injection Molded Plastic	No difference
Vacuum range	60-200mmHg	20-200 mm Hg	Similar upper limit
Suction capacity	5 L/min	5L/min	No difference
Canister volumes	0.3L/ 0.8L	0.3L/0.8L	No difference
Modes	Continuous or Variable/Intermittent Modes	Continuous or Variable/Intermittent Modes	No difference
Filters	Hydrophobic overflow protection/bacteria filter integrated into the single use collection canister	Hydrophobic overflow protection/bacteria filter integrated into the single use collection canister	No difference

510(k) Summary-Continued

This comparison shows no differences in technological characteristics and functions between the Pensar WoundPro Negative Pressure Wound Therapy System and the predicate devices.

SUMMARY OF PERFORMANCE TESTING:

The following performance data was provided in support of the substantial equivalence determination.

- Electrical Safety and Electromagnetic Compatibility (EMC)
- Software Verification and Validation Testing
- Verification and Validation Testing
- Biocompatibility Assessment

SUMMARY OF CONCLUSIONS

Substantial Equivalence for the Pensar WoundPro Negative Pressure Wound Therapy System is based on the same indications, intended use, technological features and functions as the predicate devices.