



Food and Drug Administration  
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August 8, 2016

PermeaDerm, Inc.  
c/o Aubrey Woodroof, Ph.D., M.B.A.  
Founder and CEO  
2905 Segovia Way  
Carlsbad, California 92009

Re: K153678

Trade/Device Name: PermeaDerm B, PermeaDerm CW, PermeaDerm Glove  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: July 11, 2016  
Received: July 11, 2016

Dear Dr. Woodroof:

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" (21 CFR 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

## Indications for Use

510(k) Number (if known)

K153678

Device Name

PermeaDerm B

PermeaDerm CW

PermeaDerm Glove

Indications for Use (Describe)

PermeaDerm B, CW and Glove are intended for use as wound coverings and to provide a moist wound healing environment on cleanly debrided wounds after hemostasis has been established.

PermeaDerm B is indicated for partial thickness burn wounds, donor sites and coverage of meshed autograft.

PermeaDerm CW is indicated for partial thickness wounds, pressure sores, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's, post-laser surgery, podiatric, wound dehiscence, trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds.

PermeaDerm Glove is indicated for debrided partial thickness hand burns.

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**  
**K153678 - PermeaDerm**

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**1.0 Name, Address, Phone and Fax Number of the Applicant**

PermeaDerm, Inc.  
2905 Segovia Way  
Carlsbad, CA 92009  
Phone: (760) 271-1589  
Fax: (760) 632-7162

**2.0 Contact Person**

Aubrey Woodroof, PhD, MBA  
Founder and CEO

**3.0 Date Prepared**

December 19, 2015; revised July 11, 2016.

**4.0 Device Identification**

Name: PermeaDerm  
Trade Names: Permeaderm B, PermeaDerm CW, PermeaDerm Glove  
Common Name: Wound Dressing, Drug  
Classification Name: Unclassified  
Product Code: FRO

**6.0 Predicate Devices**

Name	AWBAT Plus	Biobrane	Oasis
510(k) number	K091863	K790496	K061711
Trade Names	AWBAT Plus	Biobrane	Oasis Wound Matrix
Common Name	Wound Dressing, Drug	Wound Dressing, Collagen	Wound Dressing, Collagen
Classification Name	Unclassified	Unclassified	Unclassified
Product Code	FRO	KGN	KGN

**7.0 Device Description**

Composition and Design

PermeaDerm B, PermeaDerm CW and PermeaDerm Glove are identical in chemical composition and 3D structure. They are all composed of a monofilament nylon knitted fabric (virgin Indachi Nylon Monofilament Yarn 15/1), bonded to a thin slitted silicone membrane (Unrestricted Medical Grade Silicone, Applied Silicone, Dimethyl-Silicone-Elastomer P/N 40000). The nylon side of this dressing is coated with a mixture of hypoallergenic porcine gelatin (Gelita MedellaPro®) and a pure fraction of Aloe vera (Aloecorp Inc. Immuno-10®).

The physical differences in the two configurations (PermeaDerm B versus PermeaDerm CW and PermeaDerm Glove) are in the number and orientations of slits per unit area.

## **510(k) Summary K153678 - PermeaDerm**

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PermeaDerm B contains 2280 parallel slits (0.25" long) per square foot. PermeaDerm CW contains 4,464 slits (0.180" long) per square foot, and the rows of slits are parallel or perpendicular in orientation. PermeaDerm Glove has identical chemical and physical properties of PermeaDerm CW, except it is sewn into a glove configuration.

The slit configuration creates pores when the dressing is stretched. All configurations provide a moist wound healing environment with a slitted silicone/nylon membrane coated with gelatin and aloe vera extract.

The wound dressings are primary dressings, to be used with secondary absorbent cover dressings.

### Dressing sizes

PermeaDerm B: 5" x 10", 10" x 15", 15" x 20";

PermeaDerm CW: 2.5" x 5", 5" x 5"

PermeaDerm Glove: Range from Pediatric to XXL (designed to fit right or left hands)

### Prescription Use

They are prescription use products to be applied by a physician/ health care practitioner.

### Sterilization Information

The wound dressings are provided sterile for single-use only. Sterilization method is electron beam (E Beam) irradiation.

### Environment of Use

The devices are to be used by clinicians in health care facilities.

### Duration and type of contact

The product is to be in contact with breached skin for prolonged periods of time, thus it is categorized as a permanent contact device (Biocompatibility Contact Duration Category C).

## **8.0 Intended Use/Indications for Use**

PermeaDerm B, CW and Glove are intended for use as wound coverings and to provide a moist wound healing environment on cleanly debrided wounds after hemostasis has been established.

PermeaDerm B is indicated for partial thickness burn wounds, donor sites and coverage of meshed autograft.

PermeaDerm CW is indicated for partial thickness wounds, pressure sores, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's, post-laser surgery, podiatric, wound dehiscence, trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds.

PermeaDerm Glove is indicated for debrided partial thickness hand burns.

**510(k) Summary**  
**K153678 - PermeaDerm**

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**9.0 Summary of Testing**

Biocompatibility

Testing (per table below) demonstrated the PermeaDerm dressings are substantially equivalent in biocompatibility. Final test reports are included in the 510(k).

ISO 10993 Reference	Study
Part 5	Cytotoxicity: ISO Elution
Part 10	Maximization Sensitization: Guinea Pig
Part 10	Intracutaneous: Rabbit
Part 11	Acute Systemic Toxicity: Mouse Subacute Systemic Toxicity: Rat
Part 3	Genotoxicity Ames: Bacterial Reverse Mutation Mouse Lymphoma Mouse Micronucleus
Part 11	Pyrogenicity: Rabbit (according to USP<151>)

Sterilization and Shelf Life

Testing of the PermeaDerm dressing, according to ISO 11137-2, was performed to substantiate a 25 kGy E Beam dose, to validate the effectiveness of sterilization to assure a SAL of 10<sup>-6</sup>.

Real time shelf life testing has established a shelf life of 7 months. Additional testing to extend shelf life is ongoing.

Animal Performance

No additional animal studies were provided.

**10.0 Comparison of Technological Characteristics with Predicate Devices**

The subject and predicate devices are based on the following similar technological elements.

Intended Use

Each predicate and PermeaDerm are primary wound dressings. The specific indications fall under the same intended use, which is to act as a wound covering and provide a moist wound healing environment.

Design

Porosity: PermeaDerm dressings and all predicates except Oasis are designed to be porous.

Flexibility: PermeaDerm dressings and all predicates are designed to be flexible.

Size: The sheet form and sizes are comparable among all devices.

**510(k) Summary**  
**K153678 - PermeaDerm**

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The following technical (material composition) differences exist between the subject and predicate devices:

Nylon: All devices except Oasis contain a knitted nylon layer.

Silicone: All except Oasis contain silicone which is bonded to the nylon.

Gelatin: All except Oasis contain porcine gelatin; Oasis is processed porcine small intestine.

Aloe: All except BioBrane and Oasis contain aloe.

**11.0 Substantial Equivalence Conclusion**

The summary provided herein and the testing included in the 510(k) submission shows the PermeaDerm device has the intended use, same basic design characteristics, and similar material composition to the predicate devices. The minor differences in the specific indications do not change the intended use of the device, and the differences in material composition do not raise new questions of safety and effectiveness.

Therefore, it can be concluded the PermeaDerm devices are substantially equivalent to the noted predicate devices.