K122634

MAR 12 2013

510(k) Summary

Submitter Name:	Progressive Wound Care Technologies, LLC
Submitter Address:	125 Busbridge Cove Pooler, Georgia 31322
Phone Number: Fax Number:	912-201-8138 877-329-0079
Contact Person:	Mason Diamond, DDS Texel Fortis, LLC 150 Levinberg Lane Wayne, NJ 07470 Phone: 508-333-0108 Fax: 973-305-0213
Date Prepared:	7 March, 2013
Device Trade Name:	Iodofoam® Iodophor Foam Dressing
Common Name	Hydrophilic wound dressing
Classification Name, Number and Product Code: Subsequent Product Code:	Dressing, Wound, Drug Unclassified FRO KOZ
Predicate Devices:	Iodosorb® Gel (Perstorp AG) (KOZ): K905069 Iodoflex® Pads (Oclassen) (KMF): K940414
Device Description and	Iodofoam ® is a sterile, single use absorptive foam dressing consisting of polyvinyl alcohol (PVA) foam complexed with iodine to create a controlled release iodophor comprising 8% iodine (w/w). When applied to the wound, Iodofoam absorbs fluids, removing exudate, debris, and loose slough while providing a protective covering over the wound surface. Iodofoam® releases iodine to kill bacteria in the wound dressing upon absorbing wound fluid and changes color to indicate when the iodine is depleted
Statement of Indications for Use	The Iodofoam® Iodophor Foam Dressing is indicated for use in cleaning wet ulcers and wounds, including diabetic ulcers, pressure ulcers, arterial ulcers, venous stasis ulcers, and infected traumatic or surgical wounds and burns.

Summary of Technological Characteristics

Iodofoam® is designed to be highly absorbent while providing a protective, moist wound healing environment. As a hydrophilic foam dressing, Iodofoam® absorbs significantly more fluid than it's original weight. As an iodophor, Iodofoam® slowly releases iodine as wound fluid is absorbed. Depending upon exudate levels, iodine is released slowly for up to 24-72 hours.

When the foam is saturated with exudate repeatedly, and all iodine is released, the blue/black color of Iodofoam® changes to off-white. This is an indication to change the Iodofoam® dressing. Iodofoam may help promote wound healing by:

- Effectively removing exudate and debris from the wound bed, and
- Providing a moist wound healing environment.

In addition, the non-adherent PVA foam may also reduce pain and trauma during dressing changes, thereby encouraging patient compliance.

In distilled water under agitation at 37°C, an independent *in vitro* study was conducted to compare the iodine release profiles of Iodofoam® to the predicate devices Iodosorb® and Iodoflex®. The cumulative release of iodine (in ppm) was recorded every hour for a 12 hour duration. Both average profiles and lot specific profiles were assessed for three independent lots of each device. The results demonstrated that the cumulative release of iodine over time was reproducible between lots, and well controlled for all three devices. The cumulative release of iodine from Iodofoam® was fully bracketed between the predicate profiles of Iodoflex® and Iodosorb® at all time points. This study demonstrated the substantial equivalence of Iodofoam® to the predicate devices for reproducibility of iodine release and cumulative iodine release over time.

Biocompatibility testing (per ISO 10993) performed on the device demonstrated that the device is safe for the indications of use. Iodofoam® as well as the iodine based predicates Iodosorb® Gel and Iodoflex® all failed the MEM Cytotoxicity testing. The significance of this finding was further evaluated in an *in vivo* porcine wound healing model. In this study, application of Iodofoam was not found to delay the time to or incidence of wound healing. No significant differences between Iodofoam®, Iodoflex® and PVA controls were found. In addition, Iodofoam® was found to be non-reactive and non-sensitizing by ISO Intracutaneous Reactivity and ISO Guinea Pig Maximization testing, respectively.

Substantial Equivalence	Iodofoam® Iodophor Foam Dressing device is substantially equivalent to the predicates, Iodosorb® Gel (K905069) and Iodoflex® Pads (K940414), with respect to technical and design features. The submitted device poses no new questions about safety or effectiveness as compared to the predicate devices.
Conclusion	The information discussed above demonstrates that the Iodofoam® Iodophor Foam Dressing device is substantially equivalent to the predicate devices.
Declarations	o This summary includes only information that is also covered in the body of the 510(k). o This summary does not contain any unsubstantiated labeling claims. o This summary does not contain any raw data, i.e., contains only summary data. o This summary does not contain any trade secret or confidential commercial information. o This summary does not contain any patient identification information.

Summary of Substantial Equivalence

Feature	Iodofoam® Iodophor Foam Dressing	Iodosorb Gel (Perstorp AG)	Iodoflex® Pads (Oclassen)
510(k) Number	K122634	K95069	K940414
Class	Unclassified	I	I
Classification	Dressing, Wound, Drug	Beads, Hydrophilic for Wound Exudate Absorption	Bandage, Liquid
Regulation	Pre-Amendment	878.4018	880.5090
Product Code(s)	FRO KOZ	KOZ	KMF
Intended Use	The Iodofoam® Iodophor Foam Dressing is indicated for use in cleaning wet ulcers and wounds, including diabetic ulcers, pressure ulcers, arterial ulcers, venous stasis ulcers, and infected traumatic or surgical wounds and burns.	IODOSORB ° Gel - For use in cleaning wet ulcers and wounds such as venous stasis ulcers, pressure sores, diabetic foot ulcers, and infected traumatic and surgical wounds.	IODOFLEX ° Pads - For use in cleaning wet ulcers and wounds such as venous stasis ulcers, pressure sores, diabetic foot ulcers, and infected traumatic and surgical wounds.
Dressing Material	PVA polymer	Modified Starch polymer	Modified Starch polymer
Antimicrobial Agent	iodophor complex (8% w/w iodine)	iodophor complex (0.9% w/w iodine)	iodophor complex (0.9% w/w iodine)
Cumulative Iodine release (*in vitro* at 12 hours)	255 ppm	200 ppm	377 ppm
Iodine Dose (per cm^2 wound area)	1.8 mg (per label)	3.0 to 6.0 mg (per label)	1.9 mg (per label)
Cytotoxicity (ISO)	Fail	Fail	Fail
In Vivo Histology	No Aberration	Not Tested	No Aberration

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

Progressive Woundcare Technologies, LLC
% Texel Fortis, LLC
Mr. Mason Diamond
Regulatory Consultant
150 Levinberg Lane
Wayne, New Jersey 07470

March 12, 2013

Re: K122634
Trade/Device Name: Iodofoam® Iodophor Foam Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 05, 2013
Received: February 07, 2013

Dear Mr. Diamond:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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

Indications for Use

510(k) Number (if known): K122634

Device Name: Iodofoam® Iodophor Foam Dressing

Indications for Use:

The Iodofoam® Iodophor Foam Dressing is indicated for use in cleaning wet ulcers and wounds, including diabetic ulcers, pressure ulcers, arterial ulcers, venous stasis ulcers, and infected traumatic or surgical wounds and burns.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K122634