Safety & Effectiveness MedTrade Products AQUANOVA Super-Absorbent Dressing JUL 25 2007

Classification Name: 878 – General and Plastic Surgery – FRO (Dressing)

Contact Jonathan Ranfield - Director, Quality Assurance & Regulatory Affairs

Prepared: January 31st 2007

Description: MedTrade Products AQUANOVA Super-Absorbent is a mixture of chitosan, chitosan derivatives and structural materials to produce a soft pad woven dressing.

Chitosan is a material consisting of cellulostic polymer, poly-N-acetylglucosamine. A similar chitosan material has been self-affirmed as a GRAS (Generally Recognised As Safe) food ingredient in accordance with 21 CFR s 170.30. The GRAS report refers to safety studies in human beings and several species of animals. The studies sited represent research on the safety and use of chitosan, which have been published over a period of decades by scientists from around the world. This large body of scientific literature satisfies the requirement in 21 CFR s 170.30 (a), that a general recognition of safety requires common knowledge about the substance throughout the scientific community. Several biomedical applications of chitosan have already been reported.

Chitosan has many advantages due to its non-toxicity and biodegradability without damaging the environment. It is a biocompatible material that breaks down slowly in to a harmless product, glucosamine that can be absorbed completely by the body. However, no product will be available to break down as wet integrity studies have demonstrated that the dressing remains intact for removal from the wound.

MedTrade Products AQUANOVA Super-Absorbent Dressings are provided in sterile single use pouches. Pouches will be provided in a carton with an information leaflet.

MedTrade Products AQUANOVA Super-Absorbent Dressing is substantially equivalent to:

- Scion Cardio-Vascular Inc. Clo-sur P.A.D. K032986. It is similar to AQUANOVA in that it is a soft pad that provides an optimal wound-healing environment with exudates management. The manufacturers of Clo-sur P.A.D. also make antibacterial claims that MedTrade do not wish to make for AQUANOVA.
- Convatec's Aquacel Hydrofibre Wound Dressing K982116. It is similar in intended use to AQUANOVA, both products gel in the presence of fluids to absorb large quantities of exudate and produce a moist wound healing environment. Both dressings have the same indications for use. Aquacel is based on sodium carboxymethycellulose technology.
- MedTrade Products Celox Topical Hemostatic Granules. It is similar to AQUANOVA in absorbing large quantities of fluid to form a gel. It is also manufactured from chitosan. The product is different from AQUANOVA in its intended use for the professional market and the physical form (granules compared to a soft pad for AQUANOVA).

A table of comparative features may be found below.

JUL 25

COMPARATIVE FEATURES

Characteristic	MedTrade Products AQUANOVA Super-Absorbent Dressing	Scion Cardio-Vascular Inc. Clo-sur P.A.D.	Convatecs Aquacel Hydrofibre Wound Dressing	MedTrade Products CELOX Topical Hemostatic Granules
Chemistry	Absorbent chitosan, a material consisting of cellulostic polymer, poly-N-acetylglucosamine	Absorbent chitosan.	N/A – As sodium carboxymethylcellulose based.	Absorbent chitosan, a material consisting of cellulostic polymer, poly-N-acetylglucosamine
Physical Composition	Soft absorbent pad	Soft absorbent pad	Soft Absorbent pad	N/A - Absorbent granules
Indications For Use	Under the supervision of a healthcare professional AQUANOVA may be used for wounds such as leg ulcers (Stages I-IV), diabetic ulcers, surgical wounds (post-operative, donor sites, dermatological), burns (first and second degree), and the management of surgical or traumatic wounds which have been left to heal by secondary intention. AQUANOVA may also be used for the local management of wounds that are prone to bleeding such as wounds that have been surgically or mechanically debrided, donor sites, and traumatic wounds. AQUANOVA can be used in the control of minor bleeding.	A topical haemostat that provides an optimal wound healing environment with exudates management.	Under the supervision of a healthcare professional Aquacel may be used for wounds such as leg ulcers (Stages I-IV), diabetic ulcers, surgical wounds (post-operative, donor sites, dermatological), burns (first and second degree), and the management of surgical or traumatic wounds which have been left to heal by secondary intention. Aquacel may also be used for the local management of wounds that are prone to bleeding such as wounds that have been surgically or mechanically debrided, donor sites, and traumatic wounds. Aquacel can be used in the control of minor bleeding.	N/A for professional use as used as an emergency haemostat. However, OTC version is for lacerations, minor cuts and minor bleeding the same as AQUANOVA.

Characteristic	MedTrade Products AQUANOVA Super-Absorbent Dressing	Scion Cardio-Vascular Inc. Clo-sur P.A.D.	Convatecs Aquacel Hydrofibre Wound Dressing	MedTrade Products CELOX Topical Hemostatic Granules
	AQUANOVA Super-Absorbent OTC is indicated for minor burns, superficial cuts, lacerations and abrasions, and minor irritations of the skin.		Aquacel OTC is indicated for the exudates management of abrasions, lacerations, minor cuts, minor scalds and minor burns – taken from 510K as no OTC commercial packaging could be found.	
Packaging	Paper Pouch	Unknown from 510K summary or internet information	Paper/Poly Pouch	Foil Pouch
Sterilisation Method	Gamma Irradiation	Unknown from 510K summary or internet information	Gamma Irradiation	Gamma Irradiation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2007

Medtrade Products, Ltd.
% Mr. Jonathan D. Ranfield
Director, QA/RA
Crewe Business Park
Crewe, Cheshire CW1 6GL
United Kingdom

Re: K070175
Trade/Device Name: MedTrade Products AQUANOVA Super-Absorbent Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 13, 2007
Received: July 16, 2007

Dear Mr. Ranfield:

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.

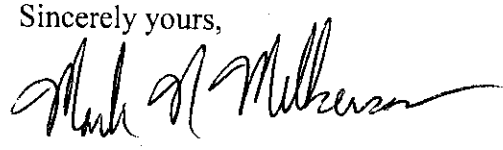
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number K070175

Device Name: MedTrade Products AQUANOVA Super-Absorbent Dressing

MedTrade Products AQUANOVA Super-Absorbent OTC is indicated for minor burns, superficial cuts, lacerations and abrasions, and minor irritations of the skin.

Prescription Use_____ _____ AND/OR Over-The-Counter Use__X___
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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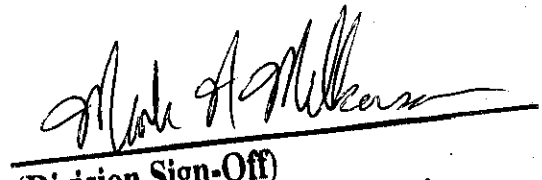
Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K071750

Indications for Use

510(k) Number K070175

Device Name: MedTrade Products AQUANOVA Super-Absorbent Dressing

Indications for Use:

Under the supervision of a healthcare professional AQUANOVA may be used for wounds such as leg ulcers (Stages I-IV), diabetic ulcers, surgical wounds (post-operative, donor sites, dermatological), burns (first and second degree), and the management of surgical or traumatic wounds which have been left to heal by secondary intention.

AQUANOVA may also be used for the local management of wounds that are prone to bleeding such as wounds that have been surgically or mechanically debrided, donor sites, and traumatic wounds. AQUANOVA can be used in the control of minor bleeding.

Aditionally, AQUANOVA may be used for exudate absorption in oncology wounds (e.g. fungating cutaneous tumours, cutaneous metastases and Kaposi's sarcomas).

Prescription Use_____X_____ AND/OR Over-The-Counter Use_ __
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)