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Medtrade

Innovative Medical Products

## 510(k) SUMMARY

**AQUANOVA Ag Super-Absorbent Dressing**

AUG 10 2010

**1. Submitter:**

Medtrade Products
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Date Prepared: March 1, 2010.

**2. Device:**

AQUANOVA Ag Super Absorbent Dressing
Silver containing Antibacterial Dressing

Common/Usual Name: AQUANOVA Ag
AQUANOVA Ag Antibacterial Dressing
AQUANOVA Ag Super Absorbent Antibacterial Dressing
AQUANOVA Ag Silver Antibacterial Dressing
AQUANOVA Ag Super Absorbent Gelling Dressing with Silver

Classification Name: Dressing, Wound, Drug

Device Class: Unclassified

Product Code: FRO

**3. Predicate Device:** AQUANOVA K070175 (Medtrade Products)
AQUACEL Ag K080383 (ConvaTec)

AQUANOVA Ag Super-Absorbent Dressing is substantially equivalent to:

MedTrade Products AQUANOVA Ag Super-Absorbent Dressing (Silver Impregnated Antibacterial Dressing) is identical to the legally marketed MedTrade Products AQUANOVA Super-Absorbent Dressing (K070175, cleared July 27, 2007) in product design, composition and processing, it is a super absorbent polymer, which is soft, sterile, non-woven pad or ribbon dressing composed of Chitosan, Chitosan derivatives and structural materials with the difference being the addition of ionic Silver.

Convatec's AQUACEL Ag Hydro fibre Wound Dressing (K080383, cleared May 2, 2008), as both products are highly absorbent polysaccharides derived polymers with the addition of ionic silver as an Antibacterial.

Therefore, the technological characteristics of the subject device are substantially equivalent to those of the predicate device and the indications for use of the subject device are substantially equivalent to the predicate device as they are both super-absorbent dressings with the addition of ionic silver, 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.

**4. Device Description:**

AQUANOVA Ag Super-Absorbent Dressing (Silver containing Antibacterial Dressing) is a soft, sterile, non-woven pad or ribbon dressing. The dressing is composed of Chitosan, Chitosan derivatives and structural materials with the addition of ionic silver. The silver ions present in the dressing help to inhibit bacterial growth in the dressing. The dressing absorbs high amounts of wound fluid and bacteria and creates a soft, cohesive gel that intimately conforms to the wound surface, maintains a moist wound environment which is

conducive to wound healing and aids in the removal of non-viable tissue from the wound (autolytic debridement). the moist wound healing environment and the ability to inhibit bacterial growth in the dressing provided by the AQUANOVA Ag Dressings support the body's healing process.

Chitosan is a material consisting of cellulostic polymer, poly-N-acetyl glucosamine. 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.

**5. Intended Use:**
Under the supervision of a healthcare professional AQUANOVA Ag may be used for the management of partial and full thickness wounds 1$^{st}$ and 2$^{nd}$ degree burns, diabetic foot ulcers, venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology and pressure ulcers/sores (partial and full thickness), surgical wounds and donor sites.

**6. Technological Characteristics:**
The composition of AQUANOVA Ag is identical to the legally marketed MedTrade Products AQUANOVA K070175, cleared July 27, 2007 in product design, composition and processing. Furthermore, AQUANOVA Ag is substantially equivalent to AQUACEL Ag K080383, cleared May 2, 2008, as both products are highly absorbent polysaccharides derived polymers with the addition of ionic silver as an Antibacterial ingredient that helps inhibit bacterial growth in the dressing. The product was evaluated through standard biocompatibility tests (ISO 10993) and found to be acceptable. Antibacterial effectiveness was established through testing with appropriate organisms.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Medtrade Products
% Mr. Jonathan Ranfield
Quality and Regulatory Director
Electra House
Crewe Business Park
Crewe, Cheshire, SW1 6GL
United Kingdom

Re: K100693
Trade/Device Name: AQUANOVA Ag Super Absorbent Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 04, 2010
Received: August 06, 2010

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. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

K100693

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Device Names: AQUANOVA Ag Super-Absorbent Dressing
Silver containing Antibacterial Dressing

**Indications for Use:**

Under the supervision of a healthcare professional AQUANOVA Ag may be used for the management of partial and full thickness wounds 1st and 2nd degree burns, diabetic foot ulcers, venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology and pressure ulcers/sores (partial and full thickness), surgical wounds and donor sites.

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)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100693