OCT 8 0 2009

K083133

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510(k) Summary
for the Andover Healthcare, Inc.
X AFD Dressings

1. SUBMITTER/510(K) HOLDER

Andover Healthcare, Inc.
9 Fanaras Drive
Salisbury, MA 01952

Contact Person: Tom Murphy, CEO
Telephone 978-465-0044

Date Prepared: August 28, 2009

2. DEVICE NAME

Proprietary Name: Andover Healthcare, Inc. X AFD Dressings
Common/Usual Name: Wound Dressings
Classification Name: Dressings

3. PREDICATE DEVICES

- SILVERSEAL® Contact wound dressing (K050649)
- Acticoat Moisture Control Dressing® (K050030)
- Mepilex Ag® Silicone-Coated Dressing (K061554)
- Polymem® Silver Wound Dressing (K031307)

4. DEVICE DESCRIPTION

The Andover Healthcare, Inc. X AFD Dressings are offered in four configurations for both over the counter use or prescription use. The dressings are described below:

CoFlex – X AFD® foam dressings are comprised of three layers: a polyurethane foam pad containing X-STATIC® metallic silver coated nylon fibers (1.5% by weight, as a preservative) evenly dispersed throughout, a waterproof and moisture vapor permeable polyurethane film layer and a latex-free cohesive elastic bandage wrap which is used to rapidly facilitate the placement and wrapping of the dressing over the wound. They are absorbent, sterile (EtO), flat, flexible and non-adherent. **CoFlex – X AFD®** dressings are designed to intimately contact the wound as a primary barrier dressing. This barrier, in combination with the X-STATIC® silver (1.5%), as determined by barrier strike through testing, prevents the penetration of microbes through the outer surface and into the dressing.

CoFlex – X AFD® First Aid foam dressings are comprised of three layers: a polyurethane foam pad containing X-STATIC® metallic silver coated nylon fibers (1.5% by weight, as a preservative) evenly dispersed throughout, a waterproof and moisture vapor permeable polyurethane film layer and a latex-free cohesive elastic bandage wrap which is used to rapidly facilitate the placement and wrapping of the dressing over the wound. They are absorbent, sterile (EtO), flat, flexible and non-adherent. **CoFlex – X AFD® First Aid** dressings are designed to intimately contact the wound as a primary dressing.

CoFlex – X AFD® Pad foam dressings are comprised of three layers: a polyurethane foam pad containing X-STATIC® metallic silver coated nylon fibers (1.5% by weight, as a preservative) evenly dispersed throughout, a waterproof and moisture vapor permeable polyurethane film layer and a latex-free cohesive elastic backing which will readily adhere to a latex-free cohesive elastic bandage wrap, rapidly facilitating the placement and wrapping of the dressing over the wound. They are absorbent, sterile (EtO), flat, flexible and non-adherent. **CoFlex – X AFD® Pad** dressings are designed to intimately contact the wound as a primary barrier dressing. This barrier, in combination with the X-STATIC® silver (1.5%), as determined by barrier strike through testing, prevents the penetration of microbes through the outer surface and into the dressing.

PowerFlex NL - X AFD® foam dressings are comprised of three layers: a polyurethane foam pad containing X-STATIC® metallic silver coated nylon fibers (1.5% by weight, as a preservative) evenly dispersed throughout, a waterproof and moisture vapor permeable polyurethane film layer and a latex-free cohesive elastic bandage wrap which is used to rapidly facilitate the placement and wrapping of the dressing over the wound. They are absorbent, sterile (EtO), flat, flexible and non-adherent. **PowerFlex NL - X AFD®** dressings are designed to intimately contact the wound as a primary dressing.

5. INTENDED USE

For over the-counter use, **PowerFlex NL - X AFD®** and **CoFlex – X AFD® First Aid** contact wound dressings are indicated for first aid management of minor abrasions, cuts, scrapes, scalds and burns.

Under the supervision of a health care professional, **CoFlex – X AFD®** and the **CoFlex – X AFD® Pad** contact wound dressings are indicated for use in light to heavy exuding partial and full thickness wounds, including decubitus and diabetic ulcers, 1st and 2nd degree burns, and donor sites. These dressings may also be used over debrided and partial thickness wounds.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Andover Healthcare, Inc. X AFD contact wound dressings are substantially equivalent in design, function and intended use to several legally marketed wound dressings including: SILVERSEAL® Contact wound dressing (K050649) (Noble Fiber Technology), Acticoat Moisture Control Dressing® (K050030) (Smith and Nephew), Mepilex Ag® Silicone-Coated Dressing (K061554) (Mölnlycke Health Care) and Polymem® Silver Wound Dressing (K031307) (Ferris Manufacturing).

All of the Andover Healthcare, Inc. X AFD contact wound dressings and all of the predicate devices are designed to intimately contact the wound as primary dressings.

For prescription use, **CoFlex – X AFD®** and the **CoFlex – X AFD® Pad** contact wound dressings as well as SILVERSEAL® Contact wound dressing (K050649), Acticoat Moisture Control Dressing® (K050030) and Polymem® Silver Wound Dressing (K031307) are indicated for use in light to heavy exuding partial and full thickness wounds, including decubitus and diabetic ulcers, 1st and 2nd degree burns, and donor sites. These dressings may also be used over debrided and partial thickness wounds.

For over the-counter use, **PowerFlex NL - X AFD®** and **CoFlex – X AFD® First Aid** contact wound dressings as well as the SILVERSEAL® Contact wound dressing (K050649) are indicated for first aid management of minor abrasions, cuts, scrapes, scalds and burns.

In design, the main difference between the predicate devices and three of the four Andover Healthcare, Inc. X AFD contact wound dressings (**CoFlex – X AFD®**, **CoFlex – X AFD® First Aid** and **PowerFlex NL - X AFD®**) is that the predicates require either using tape, a wrap or other method of fixation to secure the dressing in place, while these three X AFD dressings have a latex-free cohesive elastic bandage wrap attached which rapidly facilitates the placement and wrapping of the dressing over the wound.

The other dressing is the **CoFlex – X AFD® Pad**. It consists of only the foam pad dressing portion, without a latex-free cohesive elastic bandage wrap attached, which is the same form as the predicate devices. It requires some method of fixation to secure it in place. (A latex-free cohesive elastic bandage can be used to secure it in place as it readily sticks to the latex-free cohesive elastic bandage backing of the pad.)

It is the manner of securing the dressings in place and not the dressings themselves

that are different, and therefore the Andover Healthcare, Inc. X AFD contact wound dressings are substantially equivalent to the predicate devices.

All of the Andover Healthcare, Inc. X AFD contact wound dressings and all of the predicate devices contain silver.

The polyurethane foam pads in the Andover Healthcare, Inc. X AFD contact wound dressings contain X-STATIC® metallic silver coated nylon fibers (1.5% by weight, as a preservative). These nylon fibers are coated, up to 30% of their weight, with 99.99% pure elemental silver which affords 1.5% total silver (by weight of the foam pad) contained within the X AFD dressing. The amount of silver afforded by the X-STATIC® fibers incorporated into the Noble Fiber Technology SILVERSEAL® Contact wound dressing (K050649) is also 1.5% (by weight of the dressing). Hence the X AFD contact wound dressings are substantially equivalent to the Noble Fiber Technology SILVERSEAL® Contact wound dressing (K050649) in both type and amount of silver in the dressings.

Andover Healthcare, Inc. X AFD contact wound dressings are comprised of a polyurethane foam pad containing X-STATIC® metallic silver coated nylon fibers (1.5% by weight, as a preservative) evenly dispersed throughout. Both Mepilex Ag® Silicone-Coated Dressing (K061554) and Polymem® Silver Wound Dressing (K031307) are comprised of foam pads with silver evenly dispersed throughout. Additionally, the silver in both the Andover Healthcare, Inc. X AFD contact wound dressings and the Polymem® Silver Wound Dressing (K031307) is metallic silver. Therefore, X AFD contact wound dressings are substantially equivalent to both the Mepilex Ag® Silicone-Coated Dressing (K061554) and the Polymem® Silver Wound Dressing (K031307).

7. PERFORMANCE TESTING

The Andover Healthcare, Inc. X AFD Dressings were subjected to biocompatibility test including cytotoxicity, sensitization, and irritation. All tests were performed in accordance with Part-10993 of the International Standard Organization (ISO) Standard (Biological Evaluation of Medical Devices) by North American Science Associates Inc. (NAMSA). The studies indicate that Andover Healthcare, Inc. X AFD Dressings are safe for their intended use. Additionally, barrier strike through testing was performed demonstrating that the Andover Healthcare, Inc. X AFD Dressings prevent the penetration of microbes through the outer surface and into the dressing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Andover Healthcare, Inc.
% Dr. Valerie Dunn
R & D Technical Manager
9 Fanaras Drive
Salisbury, Massachusetts 01952

OCT 8 0 2009

Re: K083133
Trade/Device Name: Andover Healthcare, Inc. X AFD Dressings:
CoFlex -X AFD®, CoFlex –X AFD® Pad
Andover Healthcare, Inc. X AFD Dressings:
PowerFlex NL – X AFD®, CoFlex – X AFD® First Aid
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 28, 2009
Received: August 31, 2009

Dear Dr. Dunn:

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 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

for

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

Enclosure

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Indications for Use

510(k) Number (K083133):

Device Name: Andover Healthcare, Inc. X AFD Dressings:

- CoFlex -X AFD®
- CoFlex -X AFD® Pad

Indications for Use:

Under the supervision of a health care professional, CoFlex -X AFD® and the CoFlex -X AFD® Pad contact wound dressings are indicated for use in light to heavy exuding partial and full thickness wounds, including decubitus and diabetic ulcers, 1st and 2nd degree burns, and donor sites. These dressings may also be used over debrided and partial thickness wounds.

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 Kramer for MXM

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

510(k) Number K083133

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Indications for Use

510(k) Number (K083133):

Device Name: Andover Healthcare, Inc. X AFD Dressings:

- PowerFlex NL - X AFD®
- CoFlex - X AFD® First Aid

Indications for Use:

For over the-counter use, PowerFlex NL - X AFD® and CoFlex - X AFD® First Aid contact wound dressings are indicated for first aid management of minor abrasions, cuts, scrapes, scalds and burns.

Prescription Use ____ AND/OR Over-The-Counter Use_x_
(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 MXM

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

510(k) Number K083133