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Section 5 – Traditional 510(k) Device Modification - Summary

This Traditional 510(k) Device Modification is to provide substantial equivalence for the Advanced Medical Solutions Limited's Non-Adherent Antimicrobial Alginate Dressing to the predicate device Antimicrobial Alginate Dressing, 510(k) # K024298, manufactured by Advanced Medical Solutions. The modification to the existing predicate device is the addition of a perforated, non-adherent wound contact layer.

Submitted by:- Advanced Medical Solutions Limited
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Contact:- Mrs. Claire Ryan
Regulatory Affairs Manager
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Date prepared:- 11th September 2008

Common Name:- Non-Adherent Antimicrobial Alginate Dressing

Trade Names:- SILVERCEL* Non-Adherent Antimicrobial Alginate Dressing

Classification Name:- Dressing, Wound, Drug

Classification:- Unclassified

Product Code:- FRO

Legally marketed device(s) for which substantial equivalence is claimed:-
Antimicrobial Alginate Dressing, 510(k) # K024298, manufactured by Advanced Medical Solutions and Silver Alginate II Dressing, 510(k) # K041316/K063173/K070581, manufactured by Advanced Medical Solutions.

Device Description:-
Non-Adherent Antimicrobial Alginate Dressing is a sterile, non woven pad composed of a high G (guluronic acid) alginate, carboxymethylcellulose (CMC) and silver coated nylon fibres, laminated to a perforated, non-adherent ethylene methyl acrylate (EMA) wound contact layer. The dressing absorbs exudate and allows intact removal, whilst maintaining a moist wound environment. A moist wound environment is optimal for wound healing. The silver ions within the dressing protects the dressing from bacterial contamination. Odor reduction results from the antibacterial effect.

*Trademark of Johnson & Johnson

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The Non-Adherent Antimicrobial Alginate Dressing is available various sizes; 5cm x 5cm (2" x 2"), 11cm x 11cm (4¼" x 4¼"), 10cm x 20cm (4" x 8") and 2.5cm x 30.5cm (1" x 12"). The dressings are packaged in pouches or blister pots.

Indications for use:
Non-Adherent Antimicrobial Alginate Dressing is an effective barrier to bacterial penetration. The barrier functions of the dressing may help reduce infection in moderate to heavily exuding partial and full-thickness wounds, including pressure ulcers, venous ulcers, diabetic ulcers, donor sites, traumatic and surgical wounds.

Non-Adherent Antimicrobial Alginate Dressing is indicated for external use only.

Manufacturing:-
Non-Adherent Antimicrobial Alginate Dressing will be manufactured according to the product specification and under good manufacturing practices (GMP). A risk analysis has been performed to identify possible failure mode during manufacturing. Manufacturing controls have been developed and implemented to address the identified risk factors based on the criticality of the failure mode.

Advanced Medical Solutions Ltd Non-Adherent Antimicrobial Alginate Dressing meets all the established specifications prior to release to ensure the device is safe, effective and correctly labelled for its intended use.

Testing:-
The biocompatibility of Advanced Medical Solutions Limited Non-Adherent Antimicrobial Alginate Dressing has been demonstrated to be in compliance with the requirements of BS EN ISO 10993-1(Biological Evaluation of Medical Devices). Sterilisation validation has been performed in compliance with ISO 11137 standards.

Statement of Substantial Equivalence:-
The indication for use, performance testing and antimicrobial activity for the Non-Adherent Antimicrobial Alginate Dressing is substantially equivalent to the predicate devices; Antimicrobial Alginate Dressing, 510(k) # K024298 and Silver Alginate II Dressing, 510(k) # K041316/K063173/K070581, both manufactured by Advanced Medical Solutions. The biocompatibility and performance testing for the Non-Adherent Antimicrobial Alginate Dressing has demonstrated that the device is safe and effective for the indications of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 2008

Advanced Medical Solutions Limited
% Ms. Claire Ryan
Regulatory Affairs Manager
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Winsford Industrial Estate
Winsford
Cheshire
CW7 3PD
United Kingdom

Re: K081363
Trade/Device Name: Non-Adherent Antimicrobial Alginate Dressing
Regulation Number: Unclassified
Product Code: FRO
Dated: September 11, 2008
Received: September 15, 2008

Dear Ms. Ryan:

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,

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

Enclosure

K081363

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Indications for Use

510(k) Number (if known):

Device Name: **Non-Adherent Antimicrobial Alginate Dressing**

Indications for Use:

Non-Adherent Antimicrobial Alginate Dressing is an effective barrier to bacterial penetration. The barrier functions of the dressing may help reduce infection in moderate to heavily exuding partial and full-thickness wounds, including pressure ulcers, venous ulcers, diabetic ulcers, donor sites, traumatic and surgical wounds.

Non-Adherent Antimicrobial Wound Dressing is indicated for external use only.

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

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

510(k) Number K081363