Advanced Medical Solutions Ltd

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Registered in England 2666957 VAT No. GB636 5551 27

510(k) Summary Statement

Submitted by:	Advanced Medical Solutions Ltd Premier Park 33 Road One Winsford Industrial Estate Winsford Cheshire CW7 3RT Tel: +44 1606 863500 Fax: +44 1606 863600
Contact Person:	Kay M^c^Grath
Date of Summary:	25 July 2017
Trade Name:	PHMB Foam Wound Dressing
Common Name:	PHMB Wound Dressing
Classification Name:	Dressing, Wound, Drug
Classification:	Unclassified (Pre-amendment)
Classification Code:	Product code: FRO
Predicate Device(s):	Kendall™ AMD Antimicrobial Wound Dressing (K082296)

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Device Description:

The subject device, PHMB Foam Wound Dressing, is a polyurethane foam impregnated with Polyhexamethylene Biguanide (PHMB), an agent that protects the dressing from bacterial penetration and colonization.

The foam in the dressings has a microporous hydrophilic foam structure that absorbs wound exudate and maintains a moist wound healing environment.

Based on *in vitro* performance data, the PHMB Foam Wound Dressing provides a barrier to bacterial penetration through the dressing and the PHMB prevents colonization and proliferation of bacteria within the dressing while in use (<24 hours).

PHMB Foam dressings, when tested *in-vitro* have been demonstrated to be effective against the following three gram positive bacteria, three gram negative bacteria and two yeast challenge organisms within the dressing: MRSA, MRSE, VRE, *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Candida albicans and Rhodotorula mucilaginosa*.

The device is presented in Non-border (non-adhesive) and border (adhesive) versions.

The dressing is supplied sterile in a range of sizes between 4 in^2 to 64 in^2.

Indication for Use:

PHMB Foam Wound Dressings are indicated for use in the temporary management (<24 hours) of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions , lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds.

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Substantial Equivalence:

PHMB Foam Wound Dressing has substantially equivalent intended use, design, materials, labeling, and performance characteristics to the predicate device Kendall™ AMD Antimicrobial Wound Dressing (K082296).

Technological characteristics:

PHMB Foam Wound Dressing is substantially equivalent to the predicate device listed when compared to the technological characteristics such as design, materials, chemical composition, and are supplied sterile for single use.

The PHMB concentration differs between the predicate and PHMB Foam Wound Dressing, however they provide equivalent efficacious performance.

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Performance Testing Summary:

Performance data submitted in support of this 510k included *in-vitro* and animal testing.

Performance testing included total fluid handling, and peel adhesion (adhesive version only). In addition broad spectrum activity was demonstrated to be effective against the following three gram positive bacteria, three gram negative bacteria and two yeast challenge organisms within the dressing:

Methicillin-Resistant *S. aureus* (*MRSA*)

Methicillin Resistant *S. epidermidis* (*MRSE*)

Vancomycin-Resistant *E. faecalis (VRE)*

Pseudomonas aeruginosa

Escherichia coli

Klebsiella pneumoniae

Candida albicans

Rhodotorula mucilaginosa

Biological evaluation demonstrates that PHMB Foam Wound Dressings are cleared as a (Category A) limited contact device (<24 hours) in accordance with the requirements of BS EN ISO 10993-1 (Biological Evaluation of Medical Devices).

Conclusion:

Based on the information provided within this 510(k) submission, Advanced Medical Solutions Ltd. concludes that the proposed PHMB Foam Wound Dressing is substantially equivalent to the predicate device listed.