

K990810

SEP 17 1999

MAERSK MEDICAL

510(k) SUMMARY

**ARGLAES-AB™ Antimicrobial Barrier Film Dressing/
ARGLAES-AB™ Antimicrobial Barrier Island Dressing/
(79 MGP)**

1. SUBMITTER'S NAME
2. CONTACT PERSON AT MAERSK MEDICAL, LTD.
3. DATE THAT 510(k) SUMMARY WAS PREPARED
4. NAME OF THE MEDICAL DEVICE (Classification / Common / Proprietary)
5. LEGALLY MARKETED DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED
6. DESCRIPTION OF THE DEVICE
7. INTENDED USE OF THE DEVICE
8. TECHNOLOGICAL COMPARISON BETWEEN SUBJECT AND PREDICATE DEVICES
9. SUMMARY OF PRECLINICAL PERFORMANCE STUDIES AND CONCLUSIONS FROM PRECLINICAL PERFORMANCE STUDIES

1. SUBMITTER'S NAME
MAERSK MEDICAL, LTD. 26/27 Thornhill Road Redditch, Worcestershire B98 9NL ENGLAND
Tel: 011-44-1-527 587 700 Fax: 011-44-1-527 592111

2. U.S. REGULATORY CONTACT PERSON FOR MAERSK MEDICAL, LTD.
Evan Dick, Ph.D. E.G. Dick & Associates 7527 Westmoreland Avenue St. Louis, MO 63105
Tel: (314) 721-0112 Fax: (314) 721-7591

Maersk Medical Ltd., Thornhill Road
Redditch, Worcestershire B98 9NL, England

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3. DATE THAT 510(k) SUMMARY WAS PREPARED
March 11, 1999

4. NAME OF THE MEDICAL DEVICE	
Classification name	Dressing, wound and burn, occlusive (Surgery, 79 MGP)
Common / usual name	Topical wound Dressing
Proprietary names	ARGLAES-AB™ Antimicrobial Barrier Film and Island Dressings

5. LEGALLY MARKETED DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED
<p>ARGLAES-AB™ Antimicrobial Barrier Film Dressing (K970566) ARGLAES-AB™ Antimicrobial Barrier Island Dressing (K973657)</p>

6. DESCRIPTION OF THE DEVICE
<p>ARGLAES-AB™ Antimicrobial Barrier Film Dressings are sterile, visually clear, oxygen and moisture vapor permeable, and self-adherent dressings for use in wound care and venipuncture site management. ARGLAES-AB™ dressings are an effective protection against microbial contamination.</p> <p>ARGLAES-AB™ Antimicrobial Barrier Island Dressings are sterile wound dressings composed of a calcium alginate pad presented on a visually clear, self-adherent, antimicrobial barrier film backing. The ARGLAES-AB™ island dressing combines the advantages of a calcium alginate wound dressing together with ARGLAES-AB™ antimicrobial barrier film protection against wound site contamination.</p>

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7. INTENDED USE OF THE DEVICE

ARGLAES-AB™ Antimicrobial Barrier Film Dressing and ARGLAES-AB™ Antimicrobial Barrier Island Dressing are intended to be used as topical wound dressings for the local management of chronic wounds incisions, donor sites, minor burns, and abrasions and lacerations. The film dressing is also intended to be used for venipuncture site management.

8. TECHNOLOGICAL COMPARISON BETWEEN SUBJECT AND PREDICATE DEVICES

The subject devices were previously reviewed under K970566 (film dressing) and K973657 (island dressing).

The subject devices are physically identical with the wound dressings reviewed under K970566 and K973657.

The predicate devices have been shown to have "antimicrobial barrier activity".

The present 510(k) presents *in vitro*, 7-day antimicrobial barrier (strike-through) studies to: (1) support the claim of sustained antimicrobial barrier activity, and (2) extend the list of microorganisms used to challenge the antimicrobial barrier activity of ARGLAES-AB dressings.

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**9. SUMMARY OF PRECLINICAL PERFORMANCE STUDIES AND
CONCLUSIONS FROM PRECLINICAL PERFORMANCE STUDIES**

ARGLAES-AB™ Antimicrobial Barrier Film Dressing and ARGLAES-AB™ Antimicrobial Barrier Island Dressing were previously reviewed under K970566 and K973657, respectively. Studies reviewed under K970566 and K973657 showed these products to be safe for use as topical wound dressings.

In vitro, 7-day antimicrobial barrier (strike-through) tests were performed in which the ARGLAES film was challenged by the following microbial strains:

Staphylococcus aureus (MRSA, ATCC #33591)
Staphylococcus aureus (MRSA, ATCC #33593)
Staphylococcus aureus
Enterococcus faecalis (VRE)
Staphylococcus epidermidis
Enterococcus faecium
Escherichia coli
Streptococcus agalatiæa
Streptococcus pyogenes
Candida albicans
Acinetobacter baumannii
Enterobacter cloacæ
Klebsiella pneumoniae
Proteus mirabilis
Proteus vulgaris
Serratia marcescens

For each microbial strain tested, above, ARGLAES-AB film was found to demonstrate sustained antimicrobial barrier activity.



SEP 17 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Maersk Medical, LTD.
c/o E. G. Dick & Associates
7527 Westmoreland Avenue
St. Louis, Missouri 63105

Re: K990810

Trade Name: Arglaes –AB Antimicrobial Barrier Film Dressing
Arglaes –AB Antimicrobial Barrier Island Dressing

Regulatory Class: Unclassified

Product Code: MGP

Dated: June 18, 1999

Received: June 21, 1999

Dear Dr. Dick:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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). You may, therefore, market the devices, 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.

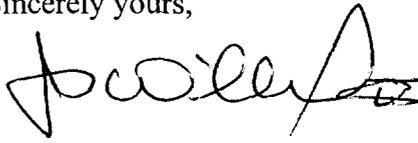
If your devices are classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Dr. E. G. Dick

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



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Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K990810

Device Name: ARGLAES-AB Antimicrobial Film Dressing
ARGLAES-AB Antimicrobial Island Dressing

Indications For Use:

FILM DRESSING

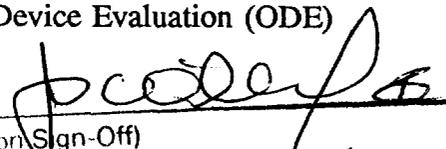
ARGLAES-AB Antimicrobial Film Dressings are sterile, transparent, and self-adherent dressings intended for the local management of pressure sores, incisions, donor sites, minor burns, abrasions and lacerations, superficial leg ulcers and other dermal ulcers.

ARGLAES-AB Antimicrobial Film Dressings are also intended to help secure and protect intravenous catheters.

- continued on second page for ISLAND DRESSINGS -

(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 Devices

510(k) Number

K990810

Prescription Use X
(per 21 CFR 801.109)

OR

Over-The-Counter Use _____

K990810

INDICATIONS FOR USE STATEMENT, continued

Product Name: ARGLAES-AB Antimicrobial Barrier Film and Island Dressings

INDICATIONS FOR USE STATEMENT
(continued)

ISLAND DRESSING

ARGLAES-AB Antimicrobial Barrier Island Dressings are sterile wound dressings composed of a calcium alginate pad presented on a visually clear, self-adherent, antimicrobial barrier film backing.

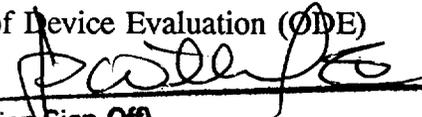
ARGLAES-AB Antimicrobial Barrier Island Dressings are intended for the local management of exuding wounds, including infected and non-infected:

- Pressure Ulcers
- Venous Ulcers
- Diabetic Ulcers
- Arterial Ulcers
- Donor Sites and other bleeding surface wounds
- Dermal lesions, trauma injuries or incisions.

ARGLAES-AB Antimicrobial Barrier Island Dressings are contraindicated for third degree burns or for use on individuals with a known sensitivity to silver.

(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 Devices

510(k) Number _____

K990810

Prescription Use X
(per 21 CFR 801.109)

OR

Over-The-Counter Use _____