

FEB 13 1998

510(k) SUMMARY
Algo plaque Film Extra Thin Hydrocolloid Dressing

K974348

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510(k) SUMMARY**ALGOPLAQUE FILM Extra Thin Hydrocolloid Dressing
(79 MGP)**

1. SUBMITTER'S NAME
2. CONTACT PERSON AT LABORATOIRES URGO
3. U.S. REGULATORY AGENT FOR LABORATOIRES URGO
4. DATE THAT 510(k) SUMMARY WAS PREPARED
5. NAME OF THE MEDICAL DEVICE (Classification / Common / Proprietary)
6. LEGALLY MARKETED DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED
7. DESCRIPTION OF THE DEVICE
8. INTENDED USE OF THE DEVICE
9. TECHNOLOGICAL COMPARISON BETWEEN SUBJECT AND PREDICATE DEVICES
10. SUMMARY OF SAFETY STUDIES AND CONCLUSIONS FROM SAFETY STUDIES
11. STERILIZATION / STERILITY ASSURANCE LEVEL

1. SUBMITTER'S NAME
Laboratoires URGO 42, rue de Longvic 21300 Chenove FRANCE
Telephone: 011-33-3-80 44 79 67 Fax: 011-33-3-80 44 71 12

2. CONTACT PERSON AT LABORATOIRES URGO
Sophie Lambert-Fortin Manager, Regulatory Affairs
Telephone: 011-33-3-80 44 79 67 Fax: 011-33-3-80 44 71 12

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3. U.S. REGULATORY AGENT FOR LABORATOIRES URGO	
Evan Dick, Ph.D. EGDA 7527 Westmoreland Avenue St. Louis, MO 63105	
Telephone:	(314) 721-0112
Fax:	(314) 721-7591

4. DATE THAT 510(k) SUMMARY WAS PREPARED
November 19, 1997

5. NAME OF THE MEDICAL DEVICE	
Classification name	<i>Dressing, wound and burn, occlusive (Surgery 79 MGP)</i>
Common / usual name	<i>Hydrocolloid dressing</i>
Proprietary name	<i>ALGOPLAQUE® FILM Extra Thin Hydrocolloid Dressing</i>

ALGOPLAQUE® FILM Extra Thin Hydrocolloid Dressing will also be distributed under the additional proprietary name *SORBEX Thin*.

6. LEGALLY MARKETED DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED
<ul style="list-style-type: none"> • ALGOPLAQUE Hydrocolloid Dressing (K970518, URGO) • DuoDERM Extra Thin CGF Dressing (K925990, ConvaTec) • Comfeel Ulcer Dressing (K840438, Coloplast)

7. DESCRIPTION OF THE DEVICE

ALGOPLAQUE FILM is a flexible, semioclusive, topical wound dressing that consists of a polyurethane backing sheet and a hydrocolloid layer. The hydrocolloid layer interacts with wound exudate - liquifying into a soft gel. This gel enables the dressing to be removed with minimal trauma to the underlying tissues.

8. INTENDED USE OF THE DEVICE

Algoplaque Film Extra Thin Hydrocolloid Dressing is a topical wound dressing that is intended for the local management of superficial, dry to lightly-exudating wounds, including pressure sores, dermal ulcers, post-operative wounds or suture sites, and abrasions and lacerations.

Algoplaque Film Extra Thin Hydrocolloid Dressings are also suitable for use as protective skin coverings.

Algoplaque Film Extra Thin Hydrocolloid Dressings are not intended for use on third degree burns.

9. TECHNOLOGICAL COMPARISON BETWEEN SUBJECT AND PREDICATE DEVICES

Algoplaque Film Extra Thin Hydrocolloid Dressings, Algoplaque Hydrocolloid Dressings (K970518), DuoDERM Extra Thin CGF Dressings (K925990), and Comfeel Ulcer Dressings (K840438) are all flexible, hydrocolloid wound dressings that consist of a polyurethane backing sheet and a hydrocolloid layer. For all of these devices, the hydrocolloid layer is composed of:

- natural polymers - primarily for absorption
- synthetic polymers - plasticizers, elastomers, tackifiers
- stabilizers - to help maintain the integrity of the final product

Algoplaque Film Extra Thin Hydrocolloid Dressing and the predicate devices are all composed, in similar proportions, of closely related natural polymers, synthetic polymers, and stabilizers.

Algoplaque Film Extra Thin Hydrocolloid Dressings are thinner than, for example, Algoplaque Hydrocolloid Dressings (K970518, URGO) and Comfeel Ulcer Dressings (K840438). Thinner dressings are more flexible and therefore easier to place upon dressing sites that require contouring (e.g., elbows). DuoDERM Extra Thin CGF Dressings (K925990) are also specially thin hydrocolloid dressings.

10. SUMMARY OF SAFETY STUDIES AND CONCLUSIONS FROM SAFETY STUDIES

ALGOPLAQUE FILM Extra Thin Hydrocolloid Dressing (Algoplaque Film Dressing) has been evaluated through *in vitro* tests and animal safety studies. All data is consistent in indicating that this product is safe for use as a topical wound dressing. The categories of safety tests and the safety test conclusions are as follows:

- Cytotoxicity - USP Agar Diffusion
 - Algoplaque Film Dressing *met the requirements of the USP*
- Cytotoxicity - USP Elution Method
 - Algoplaque Film Dressing *met the requirements of the USP*
- Hemolysis Study - *In Vitro Procedure*
 - Algoplaque Film Dressing was determined to be *nonhemolytic*
- Systemic Injection In Mice
 - Algoplaque Film Dressing *passed* the systemic injection test in mice.
- Primary Skin Irritation In Rabbits
 - Algoplaque Film Dressing is *not classified as a primary irritant or as a corrosive*
- Delayed Contact Hypersensitivity in Guinea Pigs
 - *Algoplaque Film Dressing is not a sensitizer*

11. STERILIZATION /STERILITY ASSURANCE LEVEL

Algoplaque Film Extra Thin Hydrocolloid Dressing is sterilized using beta-irradiation. The sterility assurance level (S.A.L.) for Algoplaque Film Extra Thin Hydrocolloid Dressing is 1×10^{-6} as validated according to AAMI protocol / validation criteria.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 1998

Evan G. Dick, Ph.D.
E.G. Dick & Associates
Representing Laboratoires Urgo S.A.
7527 Westmoreland Avenue
St. Louis, Missouri 63105

Re: K974348
ALGOPLAQUE® FILM Extra Thin Hydrocolloid Dressing
Regulatory Class: Unclassified
Product Code: MGP
Dated: November 7, 1997
Received: November 19, 1997

Dear Dr. Dick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 (the Act). You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled for use on third degree burns.
2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.
3. This device may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.
4. This device may not be labeled as a treatment or a cure for any type of wound.

The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81).

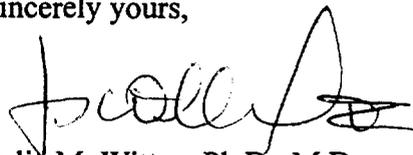
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP 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 device 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.

This letter will allow you to begin marketing your device as described in your 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 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 device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/dsmamain.html>."

Sincerely yours,



Celia M. Witten

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

K974348

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K974348

Device Name: ALGOPLAQUE FILM Extra Thin Hydrocolloid Dressing

Indications For Use:

Algo plaque Film Extra Thin Hydrocolloid Dressings are intended for the local management of superficial, dry to lightly-exudating wounds, including superficial burns, pressure sores, dermal ulcers, post-operative wounds or suture sites, abrasions and lacerations.

Algo plaque Film Extra Thin Hydrocolloid Dressings are also suitable for use as protective skin coverings.

Algo plaque Film Extra Thin Hydrocolloid Dressings are not intended for use on third degree burns.

(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

K974348

Prescription Use X
(per 21 CFR 01.109)

OR

Over-The-Counter Use _____