SECTION VI

K971337

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

JUL - 9 1997

February 28, 1997

The following constitutes a "510(k) Summary" as required by section 807.92(c).

1. Contact Person:

Tim Thomson 800.945.4994
Rynel LTD., Inc.
Route 27
Boothbay, ME 04537

2. Device name, including the trade or proprietary name if applicable, the common or usual name, and the classification name.

Trade Name - Epitech™ Island Dressing
Common name - Foam Island Dressing
Classification name - Liquid Bandage

3. Predicate device:

Rynel Medical Foam

4. Device Description including Intended Use:

The Rynel Epitech™ Island dressing pad will be manufactured from hydrophilic polyurethane foam and the border material will be either a polyurethane film or a nonwoven polyester fabric coated with a nonsensitizing acrylic pressure sensitive adhesive.

The dressing will be offered as sterile stand alone dressings and will be individually packaged. Pouch material and construction will be consistent with current packaging in use by industry to safety package sterile wound dressings.

The Rynel Epitech™ Island Dressing is intended for use in the local management of surgical incisions, lacerations, trauma inflicted wounds, abrasions, superficial burns, secondary dressings for packed wounds, and donar sites. The dressing is also appropriate for pressure, diabetic, and venous stasis ulcers. It is intended to be used to protect the skin from potential irritation, maceration, and to manage exudate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Tim Thomson
Rynel Limited, Inc.
Route 27
Boothbay, Maine 04537

JUL - 9 1997

Re: K971337
Epitech™ Island Dressing
Regulatory Class: Unclassified
Product Code: KMF
Dated: April 3, 1997
Received: April 10, 1997

Dear Mr. Thomson:

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.

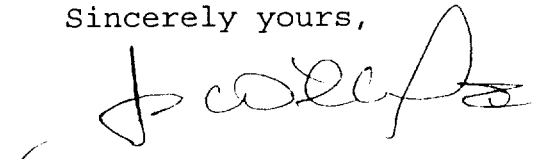
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the 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 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,



for 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

EXHIBIT A

510(k) Number (if known): K971337 U

Device Name: Epitech™ Island Dressing

Indications For Use:

The Rynel Epitech™ Island Dressing is intended for use in the local management of surgical incisions, lacerations, trauma inflicted wounds, abrasions, superficial burns, secondary dressings for packed wounds and donor sites. The dressing is also appropriate for pressure, diabetic and venous stasis ulcers. It is intended to be used to protect the skin from potential irritation, maceration and to manage exudate.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971337