

JUN 13 1996

SECTION VI

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

April 27, 1996

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

1. Contact Person:

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

Trade name - Advanced Care™ Hydrophilic Wound Dressing
Common name - Foam Wound Dressing
Classification name - Liquid Bandage

3. Predicate Device:

Rynel Medical Epitech HPF-L00562 Sterile Wound Dressing

4. Device Description Including Intended Use:

The ADVANCED CARE™ Hydrophilic Wound Dressings will be manufactured from hydrophilic polyurethane foam in various thicknesses and configurations in sizes up to 25" by 25" squares, and thicknesses from 100 mil to 0.05".

The dressings will be offered as sterile stand alone polyurethane dressings individually packaged.

The Mariner Biomedical, Inc. ADVANCED CARE™ Sterile Wound Dressing is intended for use in the local management of surgical incisions, lacerations, trauma inflicted wounds, abrasions, superficial burns, secondary dressing 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 skin from potential irritation, maceration, and to manage exudate.

5. Technological Characteristics Compared With The Predicate Device:

Physical characteristics of the ADVANCED CARE™ Wound Dressing are identical to those of the predicate device.