JAN 28 1999

K973227

II 510(k) Summary of Safety and Effectiveness In Accordance with SMDA'90

August 31, 1997

B. Braun Medical, Inc
824 Twelfth Avenue
Bethlehem, PA 18018
(610)691-5400

Contact: Mark S. Alsberge, Regulatory Affairs Director

Product Name: Askina Hydrocolloid

Trade Name: **Dressing**

Classification name:

General and Plastic Surgery
Class I, 80FRO
21 CFR 878.4060

SUBSTANTIAL EQUIVALENCE[1] TO:

510(k) number	Name	Applicant
K881050	Duoderm CGF	Convatec, Division of E.R. Squibb & Sons, Inc.

Device Description:

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, B. Braun Medical, Inc. intends to introduce into interstate commerce Askina Hydrocolloid and Askina Hydrocolloid Thin. They are multi layered dressings consisting of an absorbent hydrocolloid layer. This layer reacts with a wound exudate to form a soft gel which permits the dressing to be removed with minimal damage to newly formed tissue. Askina Hydrocolloid provides a moist wound environment while absorbing excess fluid. The moist environment is supportive to healing and promotes autolytic debridement of necrotic tissue.

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[1] The term "substantially equivalent" as use herein is intended to be a determination of substantial equivalence from an FDA -regulatory point of view under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to and does not diminish any patent claims related to this product or the technology used to manufacture the product.

K973227

Material:

Askina Hydrocolloid and Askina Hydrocolloid Thin are composed of materials that have been tested in accordance with the ISO Standard 10993 and have been determined to be suitable for the intended use of this product.

Substantial equivalence:

Askina Hydrocolloid and Askina Hydrocolloid Thin are similar in materials, form and intended use to the Duoderm CGF cleared by Convatec, Division of E.R. Squibb & Sons Inc. There are no new issues of safety or effectiveness raised by Askina Hydrocolloid and Askina Hydrocolloid Thin.

Safety And Effectiveness:

All finished products are tested and must meet all required release specifications before distribution. The array of testing required for release include, but are not limited to; physical testing, visual examination (in-process and finished product).

The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures and parameters which conform to the product design specifications.

The testing instruction records for each of the individually required procedures are approved, released, distributed and revised in accordance with document control cGMP"s.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 28 1999

Mr. Mark Alsberge
B. Braun Medical, Inc.
901 Marcon Boulevard
Allentown, Pennsylvania 18103-9341

Re: Re: K973227
Trade Name: Askina Hydrocolloid Thin
Regulatory Class: Unclassifed
Product Code: KMF
Dated: November 2, 1998
Received: November 3, 1998

Dear Mr. Alsberge:

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).

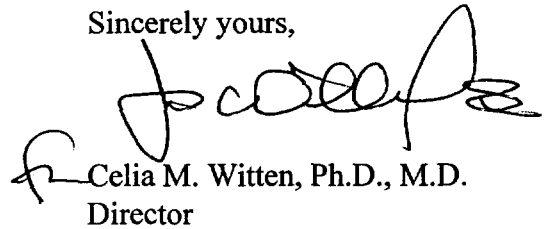
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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

Enclosure

510(k) Number (if known): K973227

Device Name: Askina Hydrocolloid/Thin

Indications For Use:

Askina Hydrocolloid and Askina Hydrocolloid/Thin react with a wound exudate to form a soft get which permits dressing removal with minimal damage to newly formed tissue. It may be used for superficial wounds e.g. minor abrasions. It may also be used for the following indications under the supervision of a healthcare professional:

- Dermal Ulcers, including
  - Partial & Full Thickness Wounds
  - Pressure Ulcers, Stages I-IV
  - Arterial and Venous Leg Ulcers
- Burns – Second Degree
- Donor Sites
- As an Aid in the Prevention of Skin Breakdown

(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 K973227

Prescription Use _____ **OR** **Over-The-Counter Use** X
(Per 21 CFR 801.109)

(Optional Format 1-2-9G)