April 9, 2024

Dow B. Hickam, Inc.
General Offices
Robin Scamuffa
Director Technical Affairs
P.O. Box 2006
Sugarland, Texas 77487

Re: K914575
Trade/Device Name: Sorbsan Topical Wound Dressing
Regulation Number: 21 CFR 878.4018
Regulation Name: Hydrophilic wound dressing
Regulatory Class: Class I
Product Code: NAC

Dear Robin Scamuffa:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 4, 1991. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code NAC.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Yu-Chieh Chiu, OHT4: Office of Surgical and Infection Control Devices, 301-796-6196, yu-chieh.chiu@fda.hhs.gov.

Sincerely,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

DEC 4 1991

Ms. Robin F. Scamuffa
Director Technical Affairs
Dow B. Hickam, Inc.
General Offices
P.O. Box 2006
Sugar Land, Texas 77487

Re: K914575
Sorbsan™ Topical Wound Dressing
Regulatory Class: Unclassified
Dated: October 24, 1991
Received: October 25, 1991

Dear Ms. Scamuffa:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. 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 without specific Food and Drug Administration (FDA) approval for such labeling.

2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization without evidence of said effect being reviewed and approved by FDA.

3. This device may not be labeled as a long-term or permanent, no change dressing, or as an artificial or synthetic skin without specific FDA approval for such labeling.

4. This device may not be labeled as a treatment or a cure for vascular stasis ulcers without specific FDA approval for such labeling.

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

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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, Title 21, Parts 800 to 895. 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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Carl A. Larson

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

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