



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2007

George H. Scherr, Ph.D.
Director
ADRI
P.O. Box 134
Park Forest, Illinois 60466

Re: K000054
Trade Name: Foam Calcium Alginate Topical
Wound Dressing with Collagen
Regulatory Class: Unclassified
Product Code: KGN
Dated: December 6, 1999
Received: January 7, 2000

Dear Dr. Scherr:

This letter corrects our substantially equivalent letter of March 13, 2000.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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 (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

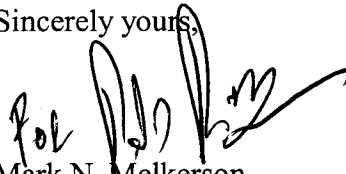
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) NUMBER (IF KNOWN): K000054
Foam Calcium Alginate Topical
DEVICE NAME: Wound Dressing With Collagen

INDICATIONS FOR USE:

CALGIFOAM calcium alginate dressings may be utilized for exudating or potentially exudating wounds such as dermal lesions or injuries, superficial cuts and wounds, dermal ulcer, or pressure sores, and stage IV wounds.

CALGIFOAM calcium alginate dressings when in contact with an exudate from a wound will form a soft colloidal gel which covers the wound, protects it, and thereby enhances the formation of granulation tissue in subsequent healing.

CALGIFOAM calcium alginate dressings are indicated for the treatment of all medium to heavily exudating wounds; for example

- ulcers of the leg
- pressure sores
- chronic wounds
- second-degree burns
- donor sites

Calcium alginate foam dressings should not be used for ulcers resulting from infection, lesions in patients with active vasculitis or third degree burns. Calcium alginate dressings are not intended for surgical implantation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K000054

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter-
(Optional Formula)