

510(k) Summary

OCT 04 2002

Contreet Hydrocolloid Dressing

Submitters name, address, phone and fax numbers

Coloplast Corporation  
1955 West Oak Circle  
Marietta, GA 30062-2249  
USA  
Phone: 770-281-8400  
Fax: 770-345-8960

Contact person at Coloplast Corp

Elizabeth Boots  
Vice President Quality Assurance  
1940 Commerce Drive  
PO Box 8300  
North Mankato, MN 56002-8300  
USA

Date 510(k) prepared

July 3, 2001

Name of the medical device

Trade name           Contreet Hydrocolloid Dressing  
Common name        Topical wound dressing  
Classification name   Dressing, wound and burn, occlusive (21CFR878.4020)

Legally marketed device to which substantial equivalence is claimed

Acticoat 7 Dressing (K001519)  
ARGLAES-AB Antimicrobial Barrier Film and Island Dressings (K990810)  
Comfeel Plus Ulcer Dressing (K941263)

Description of the device

Contreet Hydrocolloid Dressing is an antibacterial hydrocolloid dressing with silver providing an optimal moist wound healing environment.

Contreet Hydrocolloid Dressing has demonstrated in-vitro antibacterial activity in certain strains known to be detrimental to wound healing.

Contreet Hydrocolloid Dressing is a waterproof dressing with a semi-permeable film backing.

Intended use of the device

Contreet Hydrocolloid Dressing provides barrier protection against bacteria commonly encountered in wound ulcers.

Contreet Hydrocolloid Dressing is indicated for treatment of low to moderately exudating wounds.

Contreet Hydrocolloid Dressing is indicated for use for leg ulcers and pressure sores and may also be used for partial-thickness burns, donor sites, postoperative wounds and skin abrasions.

Contreet Hydrocolloid Dressing can be used on colonized wounds to support the wound healing and/or to reduce the odor from the wound.

Contreet Hydrocolloid Dressing can be used where the risk of infection is suspected or exists.

Contreet Hydrocolloid Dressing can be used on patients with wound infection at the discretion of the physician.

Contreet Hydrocolloid Dressing is suitable for use under compression bandaging on low to moderately exudating venous leg ulcers.

Summary of technological characteristics of subject device compared to predicate

Contreet Hydrocolloid Dressing compared to Comfeel Plus Ulcer Dressing: Comfeel is a hydrocolloid dressing and is the product that Contreet Hydrocolloid Dressing is based on. The only difference is that Contreet Hydrocolloid Dressing has silver incorporated into it. The indications for use that apply to Comfeel also apply to Contreet Hydrocolloid Dressing.

Contreet Hydrocolloid Dressing compared to Acticoat 7 Dressing and Arglaes-AB Antimicrobial Barrier Film and Island Dressings: All three dressings contain silver, which acts as an antimicrobial.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 04 2002

Ms. Betty Boots  
Vice President, Quality Assurance  
Coloplast Corporation  
1940 Commerce Drive  
N. Mankato, Minnesota 56003

Re: K013525  
Trade/Device Name: Contreet Hydrocolloid Dressing  
Regulatory Class: Unclassified  
Product Code: MGQ  
Dated: July 8, 2002  
Received: July 8, 2002

Dear Ms. Boots:

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 application (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 such 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.

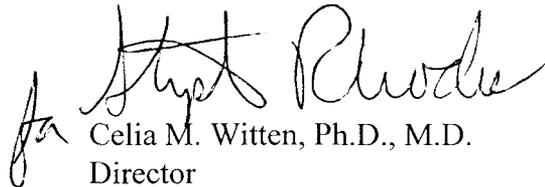
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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This letter will allow you to begin 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the printed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K 013525

Statement of indications for use

Device Name: Contreet Hydrocolloid Dressing

Indications for Use:

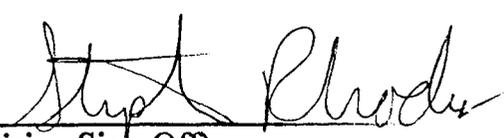
The Contreet Hydrocolloid Dressing is indicated for use in the management of low to highly exudating leg ulcers, skin tears and pressure sores. The dressing can also be used for 2<sup>nd</sup> degree burns, 2<sup>nd</sup> degree partial thickness burns, donor sites, post operative wounds and skin abrasions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)



(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K013525