MAY 17 2004

K033869

510(k) Summary

Contreet Foam Cavity Dressing

1. Submitters name, address, phone and fax numbers
2. Contact person at Coloplast Corporation
3. Date that the 510 (k) summary was prepared
4. Name of the medical device (trade, common and classification name)
5. Legally marketed device to which substantial equivalence is claimed
6. Description of the device
7. Intended use of the device
8. Summary of technological characteristics of subject device compared to predicate device
9. Non-clinical performance data
10. Conclusion

1. Submitters name, address, phone and fax numbers
Coloplast Corp 1955 West Oak Circle Marietta, GA 30062 - 2249 U.S.A.
Tel.: (770) 281 8400 Fax: (770) 281 8500

2. Contact person at Coloplast Corp
Elizabeth Boots BA, MT Quality Assurance Vice President Coloplast Corp, Skin Care Division 1940 Commerce Drive P.O. Box 8300 N. Mankato, MN 56003 - 8300 U.S.A.
Tel.: (507) 386 - 4362 Fax: (507) 345 – 3291

3. Date that the 510 (k) summary was prepared
November 14, 2003

4. Name of the medical device (trade, common and classification name)	
Trade name	**Contreet** Foam Cavity Dressing with silver
Common Name	Topical wound dressing with active ingredient
Classification name	Unclassified

5. Legally marketed device to which substantial equivalence is claimed
Contreet Foam (K022416)
Antibacterial Alginate Dressing (K024298)
Absorbent Antimicrobial Wound Dressing (K013814)
Silverlon™ Wound Packing Strips (K984210)

6. Description of the device

Contreet Foam Cavity Dressing is a highly absorbent foam cavity dressing with ionic silver as the active component in the dressing. The cavity dressing is suitable for exuding, deep wounds and is perforated to ensure flexible handling. The cavity dressing provides an optimal moist wound healing environment, combining an effective antibacterial activity in the dressing with exudates management.

7. Intended use of the device

Contreet Foam Cavity Dressing is indicated for deep, moderately to highly exuding stage II, III and IV pressure ulcers, leg ulcers, diabetic foot ulcers and burns with significant loss of tissue.

Contreet Foam Cavity Dressing maintains a moist wound environment that supports wound healing on wounds that are colonized or wounds where the risk of infection exists.

Contreet Foam Cavity dressings contain an antibacterial ingredient. The dressings demonstrate in-vitro antibacterial activity for up to 7 days. Contreet Foam Cavity Dressing is effective against certain bacterial strains known to be detrimental to wound healing.

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

8. Summary of technological characteristics of subject device compared to predicate device

Contreet Foam Cavity Dressing compared to **Contreet** Foam Dressings: **Contreet** Foam Dressings are PU-foam dressings and are the products that **Contreet** Foam Cavity Dressing is based on. The only difference is that **Contreet** Foam Cavity Dressing is indicated for deep cavity wounds.

Contreet Foam Cavity Dressing compared to Antibacterial Alginate Dressing (K024298), Absorbent Antimicrobial Wound Dressing (K013814), and Silverlon™ Wound Packing Strips (K984210):
They are all indicated for deep wounds, handle exudate, they contain silver and therefore act as an antibacterial dressing.

9. Non-clinical performance data

Contreet Foam Cavity Dressing performs as well as Contreet Foam with regard to antibacterial efficacy in certain bacteria.

Contreet Foam Cavity Dressing performs as well as Contreet Foam with regard to support reduction of the odor caused by microorganisms in the wound.

Contreet Foam Cavity Dressing is similar at absorbing exudate as Acticoat Moisture Control Dressing.

Contreet Foam Cavity Dressing is made up of the same materials as Contreet Foam dressing which has been demonstrated to be safe to use through relevant toxicological tests.

10. Conclusion
Contreet Foam Cavity Dressing is similar in function and intended use compared to the predicate devices. Contreet Foam Cavity Dressing has been demonstrated to be substantially equivalent to the predicate devices with regard to safety and effectiveness through relevant tests. Therefore Contreet Foam Cavity Dressing is considered to be substantially equivalent to the predicate devices for all purposes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2004

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

Re: K033869
Trade/Device Name: Contreet Foam Cavity Dressing with Silver
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 5, 2004
Received: March 8, 2004

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.

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), please contact the Office of Compliance at (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for 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

Indications for Use

K033869

510(k) Number (if known): K033869

Device Name: **Contreet** Foam Cavity Dressing with Silver

Indications For Use:

Contreet Foam Cavity Dressing with Silver dressings are indicated for deep wounds with moderate to high amounts of exudate.

Contreet Foam Cavity Dressing with Silver is indicated for stage II, III and IV pressure ulcers, leg ulcers, diabetic foot ulcers and first or second degree burns with significant loss of tissue.

Prescription Use ___X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K033869