

**K983042**

NOV 25 1998

**510(k) SUMMARY**

1. **DATE PREPARED**  
November 18, 1998
2. **SUBMITTER**  
Coloplast Corporation  
Skin Care Division  
1940 Commerce Drive  
North Mankato, MN 56003
3. **CONTACT PERSON**  
Harvey M. Arbit, Pharm.D., M.B.A.  
Vice President  
Research and Development
4. **NAME OF THE MEDICAL DEVICE**  
Classification Name: Dressing, Wound and Burn, Hydrogel  
Common/Usual Name: Collagen Hydrogel Wound Dressing  
  
Proprietary Name: Woun'Dres®
5. **DEVICE CLASSIFICATION**  
Regulatory Class: 2  
Product Code: MGQ SU (80)
6. **STATEMENT OF SUBSTANTIAL EQUIVALENCE**

Woun'Dres® is substantially equivalent to Carrasyn Hydrogel Wound Dressing which obtained marketing approval under 510(k) K894541 and DuoDerm Hydroactive Gel which obtained marketing approval under 510(k) K925993. Carrasyn Hydrogel Wound Dressing was found to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976.

K983042

**7. INDICATIONS FOR USE**

May be used for superficial wounds and abrasions and minor burns. Use under the supervision of health care professionals for the local management of partial- and full-thickness wounds including pressure, venous stasis, and diabetic ulcers; surgical wounds; first- and second-degree burns including management of abrasions and burns associated with dermabrasion and laser resurfacing.

**8. PHYSICAL DESCRIPTION**

Hydrogel

**9. BIOCOMPATIBILITY**

The safety and preservative effectiveness of Woun'Dres® are substantiated by the sensitization, biotoxicological and challenge tests conducted on this device as listed below:

<b>Test</b>	<b>Results</b>
Acute Dermal Toxicity Study	Not Considered Toxic
Primary Skin Irritation Test	Is not considered a primary Irritant
Delayed Contact Sensitization Study	No evidence of causing delayed contact sensitization.
Cytotoxicity Agarose overlay	Nontoxic
Hemolysis Test ( <i>In Vitro</i> )	Nonhemolytic
USP 23 <51> Anti-microbial Preservatives-Effectiveness	Meets USP 23 <51> Requirements
Bioburden	Pass
Drop Ship Test	No leakage or damage to tubes occurred.
Latex Gloves Product Compatibility	No changes imparted to Woun'Dres from the gloves and no change in strength of the gloves was observed.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Harvey M. Arbit, Pharm.D., M.B.A.  
Coloplast Corporation  
1940 Commerce Drive  
North Mankato, Minnesota 56003

Re: K983042  
Trade Name: Woun'Dres® Collagen Hydrogel Wound Dressing  
Regulatory Class: Unclassified  
Product Code: MGQ  
Dated: August 24, 1998  
Received: August 31, 1998

Dear Dr. Arbit:

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).

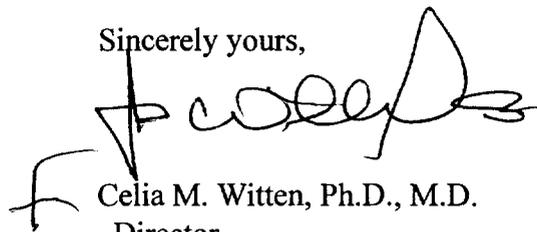
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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)-Woun'Dres® Collagen Hydrogel Wound Dressing

510(k) Number: K983042

Device Name: Woun'Dres® Collagen Hydrogel Wound Dressing

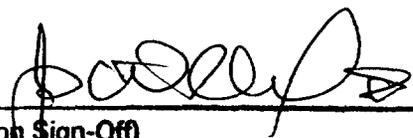
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(Please Do Not Write Below This Line-Continue on Another Page if Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ Or Over-The-Counter Use  (Per 21 CFR 801.109)



(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K983042