

MAY 22 1997

## 11.9 510(k) Summary

### **Submitter's Name and Address:**

ProCyte Corporation  
12040 115<sup>th</sup> Ave NE #210  
Kirkland, Washington 98034-6900

### **Contact person and telephone number:**

Paul Ketteridge  
Regulatory Affairs Officer  
Telephone: (206) 820-4548  
Fax: (206) 820-7611

Date summary was prepared: December 13, 1996

### **Name of the Device:**

Proprietary name: OsmoCyte™ Wound Manager Sheet Dressing  
Common name: Wound Dressing  
Classification name: Wound and Burn Dressing

### **Identification of Predicate Devices to which Substantial Equivalence is Being Claimed:**

OsmoCyte™ Wound Manager Sheet Dressing is substantially equivalent in function and intended use to the following non-classified commercially available or 510(k) cleared non-interactive wound and burn dressings:

- Kendall Curagel Hydrogel Wound Dressing
- Tielle Hydropolymer Dressing
- Elasto-Gel Hydrogel Wound Dressing
- Vigilon Primary Wound Dressing
- Flexderm Hydrogel Wound Dressing
- Inerpan Temporary Wound Dressing

### **Device Description:**

- A sterile, hydropolymer dressing which protects the wound and provides a moist wound environment for low to moderate exudating wounds.

**Explanation of how the device functions:** OsmoCyte™ Wound Manager Sheet Dressing is an absorbent dressing. It also allows the wound to remain moist. This moisture encourages autolytic-debridement which may initially increase lesion size

***Basic scientific concepts that form the basis for the device:***

OsmoCyte™ Wound Manager Sheet Dressing provides a moist wound environment and protection of the wound from the external environment.

**Statement of the Intended Use of the Device, Including General Description of the Conditions the Device Will Mitigate and the Patient Population for which the Device is Intended:**

OsmoCyte™ Wound Manager Sheet Dressing is designed to protect a wound, provide a moist environment for wound healing, and to absorb excess wound exudate. OsmoCyte™ Wound Manager Sheet Dressing is designed to provide absorbent action while maintaining a moist environment for wounds with low to moderate exudate. OsmoCyte™ Wound Manager Sheet Dressing is indicated for the management of partial and full thickness wounds, both chronic and acute, with low to moderate exudate, including the following: Pressure ulcers, diabetic ulcers, venous stasis ulcers, arterial ulcers, 1<sup>st</sup> and 2<sup>nd</sup> degree burns, donor sites, postoperative incisions, minor chemical and thermal burns, superficial lacerations, cuts and abrasions, severe sunburn, dermal lesions (e.g. poison ivy), trauma injuries or incisions.

These indication statements are not different from the predicate devices identified above.

**Statement of how the Technological Characteristics of the Device Compare to those of the Predicate Device:**

The technological characteristics of the device are similar to the predicate devices.

**Assessment of Performance Data:**

Biocompatibility testing has been performed as recommended in the "International Standard for the Biological Evaluation of Medical Devices, ISO 10993-1." These tests support the safe use of OsmoCyte™ Wound Manager Sheet Dressing as a wound dressing temporary in contact with breached or compromised skin.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 22 1997

Paul Ketteridge, R.Ph.  
Regulatory Affairs Officer  
ProCyte™ Corporation  
12040 115th Avenue N.E., Suite 210  
Kirkland, Washington 98034-6900

Re: K965143  
OsmoCyte™ Wound Manager Sheet Dressing  
Regulatory Class: Unclassified  
Product Code: MGQ  
Dated: March 25, 1997  
Received: March 27, 1997

Dear Dr. Ketteridge:

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.

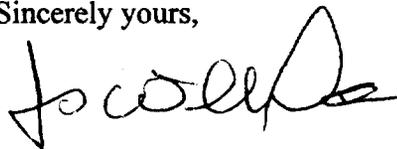
The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing 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,

  
f 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

### 3. STATEMENT OF INDICATIONS FOR USE

Page 1 of 1

510(k) Number (if known): K965143

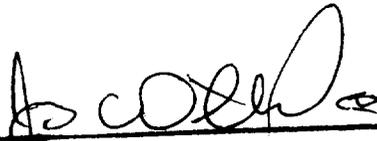
Device Name: OsmoCyte™ Wound Manager Sheet Dressing

**Indications For Use:**

OsmoCyte™ Wound Manager Sheet Dressing is indicated for the management of partial and full thickness wounds, both chronic and acute, with low to moderate exudate, including the following: Pressure ulcers, diabetic ulcers, venous stasis ulcers, arterial ulcers, 1<sup>st</sup> and 2<sup>nd</sup> degree burns, donor sites, postoperative incisions, minor chemical and thermal burns, superficial lacerations, cuts and abrasions, severe sunburn, dermal lesions (e.g. poison ivy), trauma injuries or incisions.

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K965143

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)