

DEC 10 1997

K972329

11.2 510(k) Summary

Submitter's Name and Address:

ProCyte Corporation

8511 - 154th Ave NE, Bldg A

Redmond, Washington 98052

Mailing Address:

PO Box 808

Redmond, WA 98073-0808

Contact person and telephone number:

Paul Ketteridge

Regulatory Affairs Officer

Telephone: 425-869-1239; Fax: 425-869-1229

Date summary was prepared: June 20, 1997

Name of the Device:

Proprietary name: OsmoCyte[®] RA Wound Dressing

Common name: Wound Dressing

Classification name: Wound and Burn Dressing

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

OsmoCyte[®] RA Wound 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:

- OsmoCyte[®] Pillow Wound Dressing (ProCyte)
- Elastogel[™] Island Dressing (Southwest Technologies)
- Vigilon[®] Primary Wound Dressing (Bard)
- PolyMem[®] Adhesive Urethane Dressing (Ferris)

Device Description:

Explanation of how the device functions: OsmoCyte® RA Wound Dressing utilizes a powdered polymer absorbent pad contained in a non-woven mesh pillow attached to a sheet of foam polyurethane and coated with a medical grade acrylic emulsion adhesive.

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:

Exudating wounds, infected or non-infected including pressure ulcers, diabetic ulcers, venous stasis ulcers, arterial ulcers, 1st and 2nd degree burns, donor sites, postoperative incisions, other bleeding surface wounds, dermal lesions, trauma injuries or incisions, cuts, abrasions and general first aid.

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. The ability to absorb large amounts of wound exudate is comparable to several 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® RA Wound Dressing as a wound dressing temporary in contact with breached or compromised skin.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Paul Ketteridge
Regulatory Affairs Officer
ProCyte Corporation
PO Box 808
Redmond, Washington 98073-0808

DEC 10 1997

Re: K972150 OsmoCyte® Island Wound Dressing
K972329 OsmoCyte® RA Wound Dressing
Regulatory Class: Unclassified
Product Code: KMF
Dated: September 26, 1997
Received: September 29, 1997

Dear Mr. Ketteridge:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined the devices are 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 devices subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. These devices may not be labeled for use on third degree burns.
2. These devices may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.
3. These devices may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.
4. These devices 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 devices 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval) they may be subject to such additional controls. Existing major regulations affecting your devices 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 devices in the Federal Register. Please note: this response to your premarket notification submissions 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.

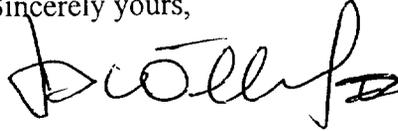
This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your devices 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 devices, 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

Page 3 - Mr. Paul Ketteridge

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 "C. Witten". The signature is fluid and cursive, with a large initial "C" and a stylized "W".

C 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

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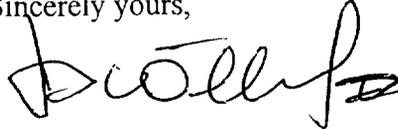
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Sincerely yours,

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C Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
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Radiological Health

Enclosure

K972329

510(k) Number (if known): K972329

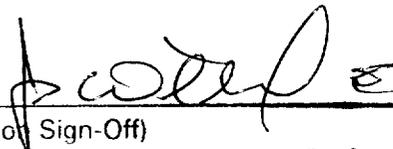
Device Name: OsmoCyte[®] RA Wound Dressing

Indications For Use:

Exudating wounds, infected or non-infected including pressure ulcers, diabetic ulcers, venous stasis ulcers, arterial ulcers, 1st and 2nd degree burns, donor sites, postoperative incisions, other bleeding surface wounds, dermal lesions, trauma injuries or incisions, cuts and abrasions.

(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 K972329

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)