K971612

MAR 16 1998

11.2 11.2 510(k) Summary

Submitter's Name and Address:

ProCyte Corporation
12040 115th 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: April 29, 1997

Name of the Device:

Proprietary name:	Osmo/PCA Pillow Wound Dressing
Common name:	Wound Dressing
Classification name:	Wound and Burn Dressing

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

Osmo/PCA Pillow 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
- Iamin® Hydrating Gel

Device Description:

Explanation of how the device functions: Osmo/PCA Pillow Wound Dressing utilizes the hydrophilic polymer granules contained in a mesh pillow to absorb up to 20 times their weight in wound exudate. Since the granules are contained in the mesh pillow, they are easily removed, thereby significantly reducing the possibility of retaining granules within the wound and allowing the Osmo/PCA Pillow Wound Dressing to be utilized in wounds with deep cavities or tunnels.

Basic scientific concepts that form the basis for the device: Osmo/PCA Pillow Wound Dressing contains a highly absorptive polymer able to absorb up to 20 times its weight in wound exudate.

Significant physical and performance characteristics of the device such as device design, materials used, and physical properties: Osmo/PCA Pillow Wound Dressing contains highly absorptive polymer granules able to absorb up to 20 times their weigh in wound exudate. The granules are encased in an inert low density polyethylene mesh fabric which allow the wound exudate to pass through and be absorbed by the polymer granules but which contains the granules, thus allowing for the dressing's easy removal from cavity or tunnel wounds.

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:

A highly absorptive pillow dressing for the management of exudating wounds, infected and 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.

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, coupled with the ability to be used safely in deep cavity or tunnel wounds is comparable to several the predicate devices. In addition, Osmo/PCA Pillow Wound Dressing has the advantage, by using an inert LDPE mesh, containing the absorbent granules, to assuring its complete removal from the wound.

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 Osmo/PCA Pillow Wound Dressing as a wound dressing temporary in contact with breached or compromised skin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 1998

Mr. Paul Ketteridge
Regulatory Affairs Officer
Procyte Corporation
12040 115th Avenue NE, Suite 210
Kirkland, Washington 98034-6900

Re: K971612
Trade Name: OSMO/PCA Pillow Wound Dressing
Regulatory Class: Unclassified
Product Code: KMF
Dated: January 12, 1998
Received: January 16, 1998

Dear Mr. 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).

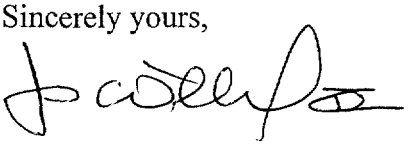
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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,



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

INDICATIONS FOR USE

510(k) Number (if known): K971612

Device Name: OSMO/PCA Pillow Wound Dressings

Indications For Use:

Indications:
Exudating wounds, including pressure ulcers, diabetic ulcers, venous stasis ulcers, arterial ulcers, 1st and 2nd degree burns, donor sites, postoperative incisions, 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 K971612

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

(Optional Format 1-2-96)