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Summary
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510(k) Summary

Submitter's Name and Address:

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Name of the Device:

Proprietary name:	OsmoCyte™ Ultra/PE Pillow Wound Dressing
Common name:	Wound Dressing
Classification name:	Wound and Burn Dressing

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

OsmoCyte™ Ultra/PE 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:

- HyQ Wound Dressing (Kingston Technologies)
- Allevyn Cavity Dressing (Smith + Nephew)
- Kaltostat Wound Packing (Calgon Vestal)
- Aquacel (Convatec)
- Sorbsan Topical Wound Dressing (Dow Hickam)

Device Description:

Explanation of how the device functions: OsmoCyte™ Ultra/PE Pillow Wound Dressing utilizes the hydrophilic polymer granules contained in a mesh pillow to absorb many 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 OsmoCyte™ Ultra/PE Pillow Wound Dressing to be utilized in wounds with deep cavities or tunnels.

Basic scientific concepts that form the basis for the device: OsmoCyte™ Ultra/PE Pillow Wound Dressing contains a highly absorptive polymer able to absorb many times its weight in wound exudate.

Significant physical and performance characteristics of the device such as device design, materials used, and physical properties: OsmoCyte™ Ultra/PE Pillow Wound Dressing contains highly absorptive polymer granules able to absorb many times their weight 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:

An 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, OsmoCyte™

Ultra/PE 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 OsmoCyte™ Ultra/PE Pillow Wound Dressing as a wound dressing temporary in contact with breached or compromised skin.