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K961758

CARRINGTON

Device Name:

Classification Name: Dressings, wound and burns, hydrogel

Common Name: Hydrogel Wound Dressings

Proprietary Names: Carrasyn® Hydrogel Wound Dressing
CarraGauze® Pads
CarraGauze® Strips
The Carrington™ Patch
CarraSorb™ M Freeze-Dried Wound Dressing

Device Sponsor: Carrington Laboratories, Inc.
2001 Walnut Hill Lane
Irving, TX 75038-4404
Registration No: 162544

Regulatory Classification: Unclassified. (Product code MGQ)

Summary of Safety and Effectiveness:

This 510 (k) Premarket Notification provides for the standardization and clarification of previously cleared indications for the labeling of Carrasyn® wound dressings. Carrasyn® Hydrogel Wound Dressing was originally marketed pursuant to 510 (k) Number K902345. The additional wound dressings that are included in this labeling standardization and clarification include CarraGauze® pads (K915001), CarraGauze® strips (K925002), The Carrington™ Patch (K933741) and CarraSorb™ M Freeze-Dried Wound Dressing (K944427).

Carrasyn™ wound dressings are either smooth, nonoily clear hydrogels or freeze-dried preparations of the same. They are supplied in either a liquid or dry state and are intended for the management of wounds.

Since the products are for use in wounds, the safety of these wound gels was established through standard biocompatibility tests. These biocompatibility tests were conducted in standard animal models with preparations of the Carrasyn® wound dressings. These tests included Primary Dermal Irritation testing and Primary Eye Irritation testing. These studies demonstrated that Carrasyn® wound dressings are not primary dermal irritants or primary eye irritants. These studies were conducted in conformance with Good Laboratory Practices (GLP) regulations of the United States Food and Drug Administration (21 CFR, Part 58).

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Clinical experience to date has been gained during the course of two studies that involved four patients with radiation dermatitis and 30 with diabetic ulcers. Grades III or IV diabetic ulcers of the foot were treated with Carrasyn® Hydrogel Wound Dressing for 10 weeks. Acute and subacute radiation dermatitis was treated for various times with Carrasyn® Hydrogel Wound Dressing. These studies evaluated the acceptability of Carrasyn® Hydrogel Wound Dressing to both the patients and clinicians, to wound and skin appearance, and to the wound healing environment. These studies concluded that Carrasyn® wound dressings are safe and effective for their intended use.

Two clinical trials have been conducted to date using The Carrington Patch™. The first clinical trial was a randomized, double-blind, active-controlled study involved 60 healthy volunteer patients with at least one aphthous ulcer less than 48 hours duration. The patients were randomly assigned to two groups where one group of 30 patients were treated with The Carrington™ Patch and one group of 30 patients treated with a control. The patients were asked to apply the dressings topically four times per day and keep a diary as to the overall degree of discomfort and complete an adverse report form. Treatment was continued until the ulcers were healed. The Carrington Patch™ was found to reduce discomfort and no adverse events were reported in association with its use.

The second clinical study was an open-label, uncontrolled study involving 30 healthy volunteer patients with at least one aphthous ulcer less than 48 hours duration. All patients were treated The Carrington™ Patch. The patients were asked to apply the dressings topically four times per day and keep a diary as to the overall degree of discomfort and complete an adverse report form. Treatment was continued until the ulcers were healed. The Carrington Patch™ was found to significantly reduce discomfort within 2 minutes and no adverse events were reported in association with its use.

The above studies demonstrate that Carrasyn® wound dressings are safe for their intended use and have not been associated with adverse events. These products are concluded to be a safe and effective dressings in the management of wounds.