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510(k) SUMMARY

1. DATE PREPARED

February 27, 1997

2. SUBMITTER

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3. CONTACT PERSON

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4. NAME OF THE MEDICAL DEVICE

Classification Name:	Bandage, Compression
Common/Usual Name:	Compression Bandaging System
Proprietary Name:	DYNA-FLEX* Multi-Layer Compression System

5. DEVICE CLASSIFICATION

Regulatory Class:	Unclassified
Product Code:	MCY

6. STATEMENT OF SUBSTANTIAL EQUIVALENCE

The DYNA-FLEX* Multi Layer Compression System is substantially equivalent and identical in function to the Wound Care Compression System (WCCS) marketed by Suncoast Medical Products.

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7. INDICATIONS FOR USE

DYNA-FLEX* Multi-Layer Compression System is indicated for the management of venous leg ulcers and related conditions. The compression system may be used on patients with an ankle circumference of 18 cm or larger (padded). Compression data indicates that the DYNA-FLEX* Multi-Layer Compression System provides sustained compression for up to seven days at both the ankle and below the knee, when used according to package insert directions.

The DYNA-FLEX Multi-Layer Compression System should not be used on diabetic patients with advanced small vessel disease, patients with lymphadema as a result of cancer, or on patients with an ankle:brachial index (ABI) of less than 0.8 . Doppler ultrasound is recommended to rule out arterial disease.

8. PHYSICAL DESCRIPTION

The DYNA-FLEX* Multi-Layer Compression System is a kit that is comprised of one wound dressing component and three bandage layers for the management of venous leg ulcers and related conditions and is packaged in a polyethylene resealable bag. The description of each of these components/bandage layers is as follows:

- The wound dressing component is the ADAPTIC* Non-Adhering Dressing (Sterile). This non-adherent 5" x 9 " pad is impregnated with a petrolatum emulsion and is packaged in a polyester polyethylene film that is heat sealed prior to sterilization.
- The first bandage layer is the DYNA-FLEX* Layer One (Padding/Absorption Layer). This polyurethane stretch foam/cotton wrap (non-sterile) is packaged in a polyurethane shrink wrap. Layer One is supplied in a 4" x 156" roll. (unstretched).
- The second bandage layer is the DYNA-FLEX* Layer Two (Compression Bandage). This non-sterile compression wrap is comprised of absorbent yarns knitted with elastomeric and nylon yarns and is packaged in a polyurethane shrink wrap. Layer Two is supplied in a 4" x 90" roll (unstretched). To assist the healthcare professional in wrapping, this bandage layer is knitted with a rectangle design, such that as the bandage is extended it will change to a square design thus indicating a satisfactory compression range.
- The third bandage layer is the DYNA-FLEX* Layer Three (Cohesive Compression Bandage). This non-sterile cohesive compression bandage is comprised of a nonwoven fabric with spandex elastic yarns bonded with a natural rubber cohesive latex based system. Layer Three is supplied in a 4" x 216" roll (stretched).

9. BIOCOMPATIBILITY

Safety tests conducted in accordance with ISO 10993 Part-1 "Biological Evaluation Of Medical Devices" demonstrate the DYNA-FLEX* Multi-Layer Compression System is non-sensitizing, non-cytotoxic, non-systemic toxic, non-irritating and is suitable for its intended use. In addition, testing was done to demonstrate that sustained compression for up to seven days at both the ankle and below the knee was maintained, when used according to package insert directions.

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