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K961426

510(k) SUMMARY

1. APPLICANT

Bio Compression Systems, Inc.
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2. DEVICE NAME

PROPRIETARY/TRADE NAME: Bio Boost™

COMMON/USUAL NAME: Intermittent Compression System; Extremity Pump; Pneumatic Therapy Device

CLASSIFICATION NAME: Powered Inflatable Tube Massager.

3. PREDICATE DEVICE

The Bio Boost™ is substantially equivalent to the Talley Intermittent Multicom™ Compression System With Calf Applicator (510(k) number K915638).

4. DESCRIPTION OF THE BIO BOOST™

The Bio Boost™ provides intermittent compression therapy for control, management and treatment of a range of lower limb conditions. The stimulation provided by the compression action improves circulation to the area treated. The Bio Boost™ is initially inflated by manually squeezing an inflation bulb. Use of different inflation bulbs provides a different baseline pressure. Thereafter, the compression action is powered by the walking action of the wearer, which exerts pressure on a pad underneath the foot. With each step, the air in the pad provides

an inflation "boost," thus delivering intermittent compression therapy to the patient's lower limb. The Bio Boost™ is made of thermoplastic poly-ether-urethane and nylon, with velcro fasteners.

5. INTENDED USE

Like other Powered Inflatable Tube Massagers, the Bio Boost™ provides intermittent compression therapy for control, management and treatment of lower limb conditions such as lymphedema of the lower limb, edema from sports injuries, and venous insufficiency. Devices providing intermittent compression therapy have been marketed for many years for these indications.

6. TECHNOLOGICAL DIFFERENCES FROM PREDICATE DEVICE

The only significant difference between the Bio Boost™ and other Powered Inflatable Tube Massagers such as the Talley Intermittent Multicom™ Compression System With Calf Applicator, is that the Bio Boost™ does not require an electric power source. As described above, the initial inflation of the Bio Boost™ is done manually, with an inflation bulb. Subsequent compression action comes from the walking action of the wearer. This modification has no significant effect on the device's performance relative to the predicate device. While the Bio Boost™ offers pressures comparable to many electrically-powered massagers, it does not utilize an electrical power source. This eliminates concerns related to potential electrical shock due to leakage or excess current. A table comparing the design, material, physical characteristics, and intended uses of the devices is attached as Exhibit A.

SPECIFICATIONS

BIOBOOST	<u>TALLEY INTERMITTENT UNIT WITH CALF APPLICATOR</u>
<p>INDICATIONS</p> <p>Lymphedema of the lower limbs Edema following trauma and sports injuries Post immobilization edema Prophylaxis of deep vein thrombosis Venous insufficiencies</p>	<p>INDICATIONS</p> <p>Lymphedema of the lower limbs Edema following trauma and sports injuries Post immobilization edema Prophylaxis of deep vein thrombosis Venous insufficiencies</p>
<p>CONTRAINDICATIONS</p> <p>Acute pulmonary edema Acute thrombophlebitis Acute congestive cardiac failure Acute infections</p>	<p>CONTRAINDICATIONS</p> <p>Acute pulmonary edema Acute thrombophlebitis Acute congestive cardiac failure Acute infections</p>
<p>MODE OF COMPRESSION</p> <p>Intermittent.</p>	<p>MODE OF COMPRESSION</p> <p>Intermittent.</p>
<p>POWER SOURCE</p> <p>Pressure from patient ambulation.</p>	<p>POWER SOURCE</p> <p>For Multicom Power Unit Electricity Supply: 220/250V50Hz (other voltages available) Electricity Consumption: 8 watts</p> <p>For Pressure Therapy Units (Cat. Ref. PT101) Electricity Supply: 200/250V50Hz Electricity Consumption: 52 watts</p>
<p>THERAPY TIME</p> <p>Continuous when walking. Unit can be worn all day.</p>	<p>THERAPY TIME</p> <p>30, 60, 120 minutes. or continuous.</p>
<p>MAXIMUM AND MINIMUM PRESSURE</p> <p>0-40 mm/Hg initial fill, and sustained during therapy (depending upon pressure bulb used). 80 mm/Hg maximum total pressure.</p>	<p>MAXIMUM AND MINIMUM PRESSURE</p> <p>0-150 mmHg.</p>
<p>NUMBER OF CHAMBERS</p> <p>Single Chamber.</p>	<p>NUMBER OF CHAMBERS</p> <p>1 to 10 chambers.</p>

BIOBOOST	TALLEY INTERMITTENT UNIT WITH CALF APPLICATOR
COMPRESSION CYCLE TIME Varies with rate at which patient walks.	COMPRESSION CYCLE TIME 30, 70, 110 seconds.
COMPRESSION APPLICATOR GARMENTS SLEEVE MATERIAL Thermoplastic poly-ether-urethane-coated nylon with velcro fastener on leg applicators.	COMPRESSION APPLICATOR GARMENTS SLEEVE MATERIAL Polyurethane coated nylon with zip fastener on leg applicators.