

K 964957

EISCHCO, Inc.
EISCHCO Inflatable Massager Boot
Premarket Notification Summary

FEB 24 1997

5. Device Description:

This device is an inflatable garment or boot that is intended for use on patients' lower limbs. It consists of two chambers. The upper chamber envelopes the lower extremity and the lower chamber is located under the foot.

When pressure is applied to the lower chamber by the patient's foot, air moves from the lower chamber to the upper chamber through the air passageways shaded in blue. The boot is placed on the patient and then inflated by attaching a hand pump to the port at the top of the boot. The boot is inflated to the desired pressure.

The patient repeats this process until the therapy session is completed. To deflate the boot, the patient presses inward on the valve stem with his/her finger or uses the cap that is attached to the valve. The deflated boot is then easily removed.

6. Substantial Equivalency Comparisons:

EISCHCO's Inflatable Massager Boot is substantially equivalent to Chattanooga Group's, Inc. Intermittent Compression System K832920. A comparison of EISCHCO's Inflatable Massager Boot and the predicate device in Table I shows that both devices are the same except for the method for inflating the garment.

The EISCHCO boot provides intermittent pressure to the garment by manual means, i.e. by actual exercise by the wearer. Pressing against a floor, wall, footboard of a bed, or possibly the foot rest of a wheelchair causes air to pass through the lower chamber to the upper chamber. As a result, pressure increases in the upper chamber and to the patient's limbs. The predicate device provides intermittent pressure to the garment by the presssion pump.

7. Conclusion:

The EISCHCO Inflatable Massager Boot is substantially equivalent to Chattanooga Group's, Inc. Intermittent Compression System K832920