

5. 510(k) Summary

5.1. submitter

5.1.1. Wright Linear Pump, Inc.
303 Robinson Road
Imperial, PA 15126

412 695-0800
FAX 412 695-0406

5.1.2. contact Edward J. Wright

5.1.3. prepared 5-May-96

5.2. product identification

5.2.1. trade nameWLP Solo VII

5.2.2. common namesingle-pressure compression pump

5.2.3. classification name Compressible Limb Sleeve (Class II)
21 CFR 870.5800

5.2.4. product number74JOW

5.3. equivalence

5.3.1. The proposed device is similar in design, function, and composition to existing compression pump devices such as document K874688 Huntleigh Flowtron AC200/2, document K882683 Jobst Extremity Pump System 7000, and document K914775 Talley MicroSystem/Talley.

5.3.1.1. As a single pressure system, the proposed device is simpler than existing sequential pressure or gradient sequential pressure systems for treating "simple lymphedema" or mild patient cases.

5.4. description

5.4.1. This is an electromechanical pneumatic device that employs a compressor and precision timer, regulator, and gage to inflate a sleeve appliance that fits over the patient's extremity.

5.4.2. The device is approximately 8"W x 6.75"H x 5.5"D and weighs less than 13 lbs.

5.5. intended use

5.5.1. The proposed device is to be used to improve the return circulation of body fluid that has pooled in one or more of a patient's extremities. This treatment reduces debilitating pain, swelling, ulceration, and risk of

dermatological impact, infection, and amputation.

5.5.2. Compression pumps of various kinds are in wide use in hospitals, clinics, patient homes, and elsewhere for treating acute and chronic fluid accumulation disorders.

5.5.3. Complies with physician-prescribed treatment pressures.

5.5.3.1. section 513, 801(b), 52 Stat. 1055, 90 Stat. 540-546 (21 U.J.C. 360C 371(A))

5.6. technological characteristics

5.6.1. This device is a new compression pump and appliance system which produces results similar to other single-pressure systems currently in use.

5.6.2. The proposed device is factory-preset for a maximum pressure less than 101 mm Hg.

5.7. summary of comparison

5.7.1. The proposed device is similar in terms of medical efficacy and operational function to the cited devices. The proposed device employs similar controls and features similar pressure ranges, degrees of accuracy, cycle times, and so on to those of the cited devices.

5.8. safety and effectiveness performance data

5.8.1. non-clinical test data

5.8.1.1. Cell pressure of prototype device was measured comparing on-board gauge reading to calibrated Hg manometer.

5.8.1.2. Pressure in appliance reaches the prescribed setting 10 or more seconds before the end of the cycle.

5.8.2. clinical test data

5.8.2.1. not applicable