

K961298

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4. 510(k) Summary

4.1. submitter

4.1.1. Wright Linear Pump, Inc.  
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4.1.2. contact Edward J. Wright

4.1.3. prepared 04/06/96

4.2. product identification

4.2.1. trade name..... WLP Solo VI

4.2.2. common name ..... sequential compression pump

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

4.2.4. product number..... 74JOW

4.3. equivalence

4.3.1. The proposed device is similar in design, function, and composition to existing compression pump devices such as document K830577B (Wright Linear Pump gradient), document K871271 (Huntleigh ✓ Flowpress AC300) pump, document K874688 (Huntleigh Flowtron AC 200/2), and document K921608 (Chattanooga Presssion sequential).

4.3.1.1. As a sequential pressure system, the proposed device is simpler than existing gradient pressure systems (Wright Linear Pump K830577B) for treating "simple lymphedema" or mild patient cases.

4.4. description

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

4.4.2. The device is approximately 8"W x 6.75"H x 5.5"D and weighs less than 15 lbs.

4.5. intended use

4.5.1. 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.

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

4.5.3. Complies with physician-prescribed treatment pressures.

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

4.6. technological characteristics

4.6.1. This device is a new state-of-the-art sequential compression pump and appliance system which produces better results than single-pressure systems currently in use. ✓ ✱

4.6.1.1. At end of the pressure phase of the treatment cycle, this device disengages cells in quick succession, from proximal to distal, to ensure a reverse gradient is never applied despite any slight irregularities inherent in mechanical pneumatic systems. Cell C is disengaged just *before* cell B and, in turn, B just *before* A.

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

4.7. safety and effectiveness performance data

4.7.1. non-clinical test data

4.7.1.1. Cell pressures of prototype device were measured using separate precision regulators for each appliance cell.

4.7.1.2. Pressures in each cell reach the prescribed setting 10 or more seconds before the next cell is activated.

4.7.1.3. Maximum pressure in the proximal cell (cell C) is reached before the end of the cycle and, thus, sustained.

4.7.2. clinical test data

4.7.2.1. not applicable