K961797

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# 5. 510(k) Summary

5.1. submitter

5.1.1. Wright Linear Pump, Inc.
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5.1.2. contact Edward J. Wright

5.1.3. prepared 5-May-96

5.2. product identification

5.2.1. trade name..... WLP Pro Lite

5.2.2. common name ..... gradient sequential compression pump

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

5.2.4. product number..... 74JOW

5.3. equivalence

5.3.1. The proposed device is similar in design, function, and composition to the existing compression pump from Wright Linear Pump gradient, document K830577B.

5.3.1.1. The proposed device will make use of updated, smaller, lighter components. It is in all ways functionally equivalent to the existing pump and delivers similar performance. This unit takes advantage of advances in component design.

5.4. description

5.4.1. This is an electromechanical pneumatic device that employs a compressor and precision timers, regulators, and gages to sequentially inflate a sleeve appliance that fits over the patient's extremity. This unit delivers a calibrated *gradient* pressure.

5.4.2. The device is approximately 10"W x 6.75"H x 5.6"D and weighs less than 15 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 state-of-the-art sequential gradient compression pump and appliance system which produces better results than non-gradient sequential or single-pressure systems currently in use.

5.6.1.1. This device allows the adjustment of individual cell pressures and dwell times.

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 pressures of prototype device were measured comparing on-board gauge readings to a calibrated Hg manometer.

5.8.1.2. Pressures in each *individual cell* reach the prescribed setting within ±5mm Hg from the panel gage reading.

5.8.1.3. Pressures in each cell reach the prescribed setting for that individual cell 10 or more seconds before the next cell is activated.

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

5.8.2. clinical test data

5.8.2.1. not applicable