

510(K) SUMMARY

- A) Submitter's Name:** *Cleveland Medical Devices Inc.* DEC - 4 1996
- B) Address:** 11000 Cedar Ave. Suite 439
Cleveland, Ohio 44106
- C) Phone and Fax numbers:** Phone: (216) 791-6720
Fax: (216) 791-6744
- D) Contact Person:** Tracie L. Lawrence
- E) Preparation Date:** June 26, 1996
- F) Classification Name:** Powered external limb overload warning device
- Common / Usual Name:** Pressure Measurement System
- Proprietary Name:** Foot Weight Alarm
- Classification:** Class II The classification number for this device is 89 IRN and is reviewed by the Physical Medicine Panel.
- Regulation:** 890.5575 A powered external limb overload warning device is a device intended for medical purposes to warn a patient of an overload or an underload in the amount of pressure placed on a leg.
- G) Substantial Equivalence:** The design concept of the Foot Weight Alarm is substantially equivalent in design to the BarMed Pty. Ltd. Portable Limb Load Monitor BMLLM-100
BarMed Pty. Ltd. Portable Limb Load Monitor BMLLM-100 K915 326
- H) Description:** The Foot Weight Alarm is a foot shaped insole device to fit inside the patient's shoe to warn the patient when they are putting too little or too much weight on a limited weight bearing foot. It consists of an Insole, a Shoe Pouch which laces to the shoe, a foot unit which fits in the Shoe Pouch and connects to the Insole, a data cable that is used by a health care professional to program the Foot Weight Alarm unit; and Foot Weight Alarm Calibration System used by the health care professional to program the Foot Unit.

I) Intended Use: The Foot Weight Alarm is intended for use in the weight bearing training of patients with various orthopedic and neurological disabilities, such as malunion fracture, amputation, and cerebral vascular accident. The Foot Weight Alarm helps train patients by limiting the amount of force placed on the leg or helping a patient to reach a set amount of force in order to facilitate the return to normal gait pattern.

J) Summary of Safety and Effectiveness Foot Weight Alarm:

The Summary of Safety and Effectiveness on Foot Weight Alarm used reflects data available and presented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

The Foot Weight Alarm is similar in application and operation to the BarMed LLM-100 of BarMed Pty. Ltd.

	Foot Weight Alarm	BarMed LLM-100
<i>Sensors:</i>	load sensors placed under heel and toes	load sensors placed under heel and toes
<i>Alarm:</i>	Audible	Audible
<i>Portable:</i>	Yes	Yes
<i>Monitor Dimension:</i>	9.5 x 6.0W x 2.5 cm	13 x 6W x 3 cm

The intended use and technological characteristics of these devices do not vary significantly. The safety and effectiveness of our Foot Weight Alarm is comparable to that of the other monitor.