

K952975

SEP 25 1996

Attachment E

510(k) Summary

K952975

510(k) Summary

Prevent Products Ankle Calf Exerciser & Phlebopump

General Information

| | |
|----------------|--|
| Classification | Class II |
| Trade Name | ACE/PP |
| Submitter | Prevent Products, Inc. 1167 Ottawa Avenue St. Paul, MN 55118 (612) 457-4385 |
| Contact | Carol Garcia General Manager |

Predicate Devices

Ankle Calf Exerciser from Prevent Products, Inc.
Toronto Lower Limb Model Mobilimb L2
PlexiPump from NuTech

Device Description

The ACE/PP is a compact portable exercise device with motor driven foot paddles. The product is controlled by the staff or the patient via an air switch. The paddles are driven in a natural and gentle dorsiflex motion.

Intended Use

The ACE/PP is intended to exercise the lower leg to help prevent vein thrombosis secondary to venous stasis and blood pooling in the leg. It also retains the exercise function for maintaining muscle tone and preventing stiffness in the ankle joints.

Testing

The product meets or exceeds UL 544.

Summary of Substantial Equivalence

The ACE/PP offers the user a means to exercise the lower leg and to minimize venous stasis in bedridden and immobile patients. The ACE/PP is substantially equivalent to the predicate ACE from Prevent Products, the Toronto Lower Limb CPM and the PlexiPump. The clinical indications for use are the same as well as the basic overall design.