

IMPACT

MONITORS INC.

K955034

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510 (k) Summary

Submitter: Impact Monitors, Inc.
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Device Name

Trade name: ForceGuard
Common name: Overload alarm, Limb load monitor
Classification: Alarm, Overload, External Limb, Powered

Substantially

Equivalent to:	Force Guard I	K882974	Impact Monitors, Inc.
	Pelimit	K770405	Synthes (USA)
		K792241	Colmed Ltd.

Intended Use

ForceGuard is used to sense the amount of weight applied to the plantar surface of the foot. The device alerts the wearer and/or therapist with a repeating tone when the weight exceeds the pre-selected value.

ForceGuard will be used on patients who have bone, connective tissue or soft tissue damage who also have been instructed by a physician to limit the weight being placed on a lower limb.

Device Description

ForceGuard Model 2090 consists of 3 components; electronics module, footpad, and leg band. The leg band is worn around the patient's ankle. The electronics module attaches to the leg band. The footpad, a flexible, fluid filled chamber, plugs into the electronics module and is worn under the plantar surface of the patient's foot inside suitable footwear.

The function of the leg band is to secure the electronics module to the patient's ankle. The function of the footpad is to sense the weight being placed through the patient's lower extremity. The electronics module functions as the user interface, processes information from the footpad and alarms when the weight on the footpad exceeds the selected weight.

Technological Modifications

For purposes of demonstrating substantial equivalence we are comparing the new device, ForceGuard Model 2090, to two predicate Class II devices: Force Guard I and Pelimit Overload Warning Device.

The following chart summarizes the similarities and differences:

Technological Characteristics	Model 2090 Compared to	
	<u>Force Guard I</u>	<u>Pelimit</u>
Design	similar	similar
Energy Source	same	same
Materials	similar	unknown
Control Mechanism	different	different
Weight Range	similar	similar

The new ForceGuard device design incorporates much of the prior design features with some modifications. The most significant change is the use of a microprocessor control that replaces portions of the analog circuitry. The microprocessor allows for continuous self-testing of the device.

The electronics module has become a non sterile, multi-patient component with the addition of interchangeable, single patient use footpads.

The following chart summarizes the performance characteristics comparison.

Performance Characteristics	Model 2090 ForceGuard	Predicate Device Force Guard I
Weight Selections	20, 30, 50, 70, 90	20, 30, 50, 70
Durability		
Controller	1 yr warranty	90 day warranty
Footpad	90 day warranty	90 day warranty
Energy Source	replaceable	not replaceable
Accuracy	+/- 5 lbs or up to 10%	+/- 5 lbs
Safety		
Low battery alarm	audio	audio
Malfunction alarms	audio and visual	audio
Materials	common	common

There are now both a visual and audio cue to indicate any device malfunction. The ability of the device to self calibrate while using interchangeable footpads increases the accuracy and effectiveness.

Conclusion

We have concluded that the new device, ForceGuard Model 2090 is substantially equivalent to the Force Guard I predicate device. This determination is based on the fact that the only design change that could affect safety and effectiveness is the addition of a micro controller. The modifications made to the predicate device have served to improve both the safety and effectiveness of the new ForceGuard Model 2090 device.