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SECTION 6: 510(k) SUMMARY

Premarket Notification

510(k) Summary of Safety and Effectiveness Information

DATE OF SUMMARY PREPARATION

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PROPRIETARY DEVICE NAME

AccuTread™ Shoe

COMMON NAME

Orthopedic Limb Load Monitor

CLASSIFICATION NAME

Powered external limb overload warning device

CLASSIFICATION REFERENCE

21 CFR, 890.5575

DEVICE PRODUCT CODE

89 IRN

REGULATORY CLASS

In accordance with FDA classification of powered external limb overload warning devices as Class II devices, this device is a Class II device and is thus subject to "Special Controls".

SPECIAL CONTROLS

At this time, Food and Drug Administration generated special controls and performance standards applicable to the ***AccuTread™ Shoe*** are not in force. Orthopedic Technology Research produces this device using available voluntary standards that are appropriate to the risk that Class II devices reasonably present. Materials and vendor certifications, in-house SOP's and ASTM standards are utilized as appropriate.

INTENDED USE

The ***AccuTread™ Shoe*** is intended for use as a limb load monitoring device to monitor limited weight bearing during rehabilitation of patients with insults to their lower extremities.

DEVICE DESCRIPTION

The ***AccuTread™ Shoe*** is a shoe-like enclosure, worn by patients having insults to their lower extremities. The device is intended for use to achieve benefits such as:

- protection of the affected extremity during the healing process,
- ease of mind during initial ambulation, and
- documentation of compliance or non-compliance to a prescribed weight bearing program.

These benefits derive from the patient's ability to know that he/she is not exceeding the correct amount of weight applied to the affected extremity as prescribed by their physician. The complete device consists of the following components:

- Shoe Body
- Sensor Unit
- Transmitter
- Receiver

SUBSTANTIALLY EQUIVALENT PREDICATE DEVICES

Several commercially available devices are substantially equivalent to the ***AccuTread™ Shoe*** with respect to materials, intended use, and indications for use.

Within the proposed class, the following device is most similar to the ***AccuTread™ Shoe*** and thus serves as the predicate device for comparison:

Force Guard I
Boulder Impact Monitors
K882974

SUBSTANTIAL EQUIVALENCE COMPARISON

To begin, both the ***AccuTread™ Shoe*** and **Force Guard I** are intended to provide feedback to the patient to monitor prescribed limited weight-bearing. Thus, the indications for use of the two devices are identical.

The **Force Guard I** possesses a sensor footpad which can be placed into the provided slipper or, alternatively, into a loose-fitting slipper or shoe of the patient's choice. The sensor footpad is designed to measure the force applied to the sensor by the plantar surface of the patient's foot.

As we understand, the pressure applied to the inflated sensor footpad is transferred via a hollow tube to a bridge-type strain gage transducer contained in an electronics module worn around the ankle of the patient. Within the electronics module, this signal is then routed to a comparator, which then compares the received signal to a pre-set calibrated maximum weight limit (20, 30, 50, or 70 pounds). If the force applied to the sensor exceeds the pre-set weight limit, a repeating "bell-like" tone is emitted once per second to alert the patient that the prescribed weight limit has been exceeded.

The ***AccuTread™ Shoe*** consists of a shoe-like enclosure which houses the force sensing mechanism in the wooden sole of the shoe. This force sensing unit consists of a lever mechanism which concentrates the force applied at the metatarsal and/or heel area of the shoe to a force concentrating unit. The force concentrating unit then concentrates the forces to a single force measurement which is then distributed over a force sensing resistor (FSR).

The FSR is a polymer thick film (PTF) device which exhibits a decrease in resistance with an increase in the force applied to the active surface. Thus, as increased load is applied to the FSR, the resistance decreases, in turn resulting in an increase in the kilohertz frequency of the transmitted "amplitude modulated wave" described below.

The FSR is in turn coupled to a transmitter which converts the resistance characteristic into a frequency which is transmitted to the receiver for comparison to a pre-set target frequency representing the prescribed maximum weight limit. As weight is applied to the ***AccuTread™ Shoe***, the transmitter emits a chopped carrier wave frequency at a constant 9.545 megahertz. This frequency is chopped at a rate of zero to three kilohertz, which is the "amplitude modulated wave". The amplitude modulated wave is what varies as weight is applied (kilohertz increase with an increase in the applied weight).

When the target frequency is detected, an alarm is emitted depending upon the signaling mode selected by the physician.

In directly comparing the two devices, it is important to note that the patient must wear the ***AccuTread™ Shoe*** throughout rehabilitation. This is unlike the **Force Guard I**, which allows the patient to alternatively place the footpad sensor in any loose-fitting shoe of their choice.

Another difference is in the weight limits that may be prescribed by the physician. The **Force Guard I** allows the physician to select only one of four pre-set maximum weight-bearing limits (20, 30, 50, and 70 pounds), whereas the ***AccuTread™ Shoe*** allows the physician to calibrate the device to any maximum weight limit within a 30 to 130 pound range.

The devices also differ in their means of alerting the patient when the prescribed weight limit has been exceeded. As described previously, the **Force Guard I** emits a repeating tone when the prescribed maximum weight limit is exceeded. The ***AccuTread™ Shoe*** instead allows the physician to prescribe any of three possible signaling modes to alert the wearer in such an instance. The three modes consist of an auditory, visual and vibrating mode. The physician thus may select the mode which will best serve the patient's needs. Table 1 on the following page describes each of these alarm feedback mechanisms.

The visual feedback mode of the ***AccuTread™ Shoe*** further allows the physician to set a minimum weight limit to notify the patient that a desired minimum load is being applied to the affected limb. In this operating mode, the minimum and maximum weight limits are distinguished by separate green (minimum) and red (maximum) lights that are clearly labeled on the receiver.

To conclude, based on the design concept, use of well known materials, feature comparisons to the selected predicate device, and indications for use, Orthopedic Technology Research believes that sufficient evidence exists to reasonably conclude that the ***AccuTread™ Shoe*** is substantially equivalent to existing legally marketed limb load monitor devices.

Table 1 on the following page summarizes the relevant feature comparisons between the ***AccuTread™ Shoe*** and **Force Guard I**.

TABLE 1: Feature comparisons between the ***AccuTread™ Shoe*** and **Force Guard I**

	AccuTread™ Shoe	**Force Guard I**
Intended Use	Intended for use to monitor limited weight-bearing during rehabilitation of patients with insults to their lower extremities by providing feedback to the wearer.	Intended for use to monitor limb load by sensing the amount of force applied to the plantar surface of the foot and to provide feedback to the wearer.
Feedback Mechanism	*Auditory:* receiver emits a "beep" (21 db) when pre-set maximum is exceeded. *Visual:* green light when pre-set minimum is achieved; red light to alert patient that pre-set maximum has been exceeded. *Vibratory:* receiver vibrates when pre-set maximum is exceeded.	*Auditory:* a repeating "bell-like" tone repeated once per second (75 db) when the selected load sensitivity is exceeded.
Summary Device Description	Shoe Body containing a sensor unit in the wooden sole to measure applied loads; separate receiver unit for calibration and to provide feedback to the wearer.	Non-skid slipper; pressure sensor footpad; electronics module to monitor weight-bearing and provide feedback to the wearer.
Force Measuring Mechanism	Pressure sensing unit housed in the sole of the shoe body. The measured force is transmitted to the receiver to provide feedback to the wearer.	Pressure sensor footpad connected to a separate bridge strain gage transducer contained in the electronics module.
Load Sensitivity	Physician calibrates the device to both a minimum and maximum prescribed load sensitivity within a 30 to 120 pound range.	One of the following four load sensitivities may be selected by the physician: 20, 30, 50, and 70 pounds.
Precision	Force Sensing Resistor (FSR) within +/- 5%	Factory set, +/- 5 pounds
Power	*Receiver:* two AA batteries. *AccuTreadShoe:* 9 volt Battery	*Electronics Module:* 9 volt battery
Low Battery Indication	*Receiver:* yellow indicator light is activated when the receiver battery is low. *Shoe:* the user is instructed to periodically check the shoe battery by applying enough weight to activate the selected signaling mode.	*Electronics Module:* a high frequency signal is emitted at twice the rate as the excess weight signal.
Manufacturer	Orthopedic Technology Research, Inc.	Boulder Impact Monitors, Inc.
510(k) Number	N/A	K882974