510(k) Summary per 21 CFR §807.92

ViaTherm BOOST Diathermy System

Submitter's information

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Classification

The classification for the new device is shown in the table below.

21 CFR Reference	Product Code	Class	Generic Device Name	Classification Description
§890.5290	IMJ	2	Diathermy, Shortwave, For Use In Applying Therapeutic Deep Heat	Shortwave diathermy

New device

The indications for use statement for the new device is shown in the table below.

K Number	Product Code	Device Name	Indications for Use
K173300	IMJ	ViaTherm BOOST Diathermy System	To generate deep heating within body tissues for the treatment of conditions such as relief of pain and muscle spasms.

Predicate device

The predicate device for the ViaTherm BOOST Diathermy System is shown in the table below.

K Number	Product Code	Predicate Device Name	Indications for Use
K020227	IMJ	Selicor D100	To generate deep heating within body tissues for the treatment of conditions such as relief of pain, muscle spasm, and joint contractures.

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ViaTherm BOOST Diathermy System, Continued

Device description

The ViaTherm BOOST Diathermy System is a single-patient reusable device designed to be self-administered in the home by a non-technical, adult operator.

Diathermy is the controlled production of "deep heating" beneath the skin in the subcutaneous tissues, deep muscles and joints for therapeutic purposes. The ViaTherm BOOST Diathermy System is a portable diathermy heat therapy system that uses a shortwave radiofrequency signal to provide diathermic heating of tissue.

The ViaTherm BOOST Diathermy System consists of five (5) components:
- Power generator
- Heat applicator garment
- Battery charging cable
- Velcro extender strap
- Cotton pad

Electronic circuitry in the power generator components generates a radiofrequency (RF) signal at a frequency of 13.56 Megahertz (MHz). The radiofrequency signal is delivered to the heat applicator garment that uses induction coil (magnetic field) technology to produce electromagnetic fields external to the applicator. This energy is converted into heat by electromagnetically resistant body tissues.

The power generator consists of a battery pack, voltage regulators, a power control and analogue sensor module, and an RF generator. A shielded 1/4” cable with 50 Ohms impedance connects the power generator to the heat applicator garment. The electrode consists of two flat spirals incorporated into the applicator garment. The spirals are each tuned to 50 Ohms. The power from the generator is split and sent to the two spirals, one of which is driven 180 degrees out of phase from the other.

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Characteristics The table below lists the characteristics for both the new and predicate devices.

Attribute	Selicor Inc. Shortwave Diathermy System K020227	ViaTherm Therapeutics LLC ViaTherm BOOST Diathermy System K173300
Intended Use/Indications For Use	To generate deep heating within body tissues for the treatment of conditions such as relief of pain, muscle spasms, and joint contractures.	To generate deep heating within body tissues for the treatment of conditions such as relief of pain and muscle spasms.
Trade/Device Name	SeliTherm D100	ViaTherm BOOST Diathermy System
Regulation Number	21 CFR 890.5290	21 CFR 890.5290
Regulation Name	Shortwave Diathermy Device	Shortwave Diathermy Device
Product Code	IMJ	IMJ
Target Population	Adults (not to be used on children) whose medical conditions would be treated, in whole or in part, with therapeutic warmth. Some examples of these types of medical conditions are as follows: pain and swelling in soft tissue injuries; muscle spasms or pain due to injury or over-training; and rehabilitation of joints from injury or.	Adults (not to be used on children) whose medical conditions would be treated, in whole or in part, with therapeutic warmth. Some examples of these types of medical conditions are as follows: pain and swelling in soft tissue injuries; muscle spasms or pain due to injury or over-training.
Intended Environment For Use	Designed for home use by a non-technical operator with or without the immediate supervision of a healthcare practitioner.	OTC device intended for use by patients in non-clinical environments, including the home
Design	User-friendly device designed with safety mechanisms that enable it to be effectively and safely operated by a non-technical adult in a non-clinical setting,	User-friendly device designed with safety mechanisms that enable it to be effectively and safely operated by a non-technical adult in non-clinical environments, including the home setting.
Mechanism of Action	Deep heating of tissue by therapeutic application of radio frequency electrical currents	Deep heating of tissue by therapeutic application of radio frequency electrical currents
Anatomical Site	Various therapy garment sizes	Multi-use therapy garment for

Attribute	Selicor Inc. Shortwave Diathermy System K020227	ViaTherm Therapeutics LLC ViaTherm BOOST Diathermy System K173300
Locations	for target locations: hand, forearm, knee, shoulder, lower back, thigh, foot, or lower leg garment	target location areas of 5 to 18 square inches: Arm (e.g. bicep, wrist, forearm), back, shoulder, leg (e.g. thigh, knee, calf), foot.
Treatment time	30 minutes	40 -45 minutes
Available Warming Control	Knob to adjust therapy duration and intensity settings	Single setting. Not adjusted by patient.
Thermal performance	Achieves 4°C temperature rise at 20 minutes	Achieves 4°C temperature rise at 25 minutes
Materials	Generator Family of anatomically designed therapy garments • Composed of nylon foam material with Spandex inner liner. The outer cover is nylon, Cordura Material, by DuPont Charger Cord Patient Interface - paper	Generator Therapy Garment Material • Futuro™ by 3M, composed of polyurethane foam, nylon, polyester, polyethylene, and spandex • Velcro Extender Strap Charger Cord Patient Interface – 100% cotton
Safety Factors	The SeliTherm C 100 requires the operator to interact with the device by pushing a button every 20-minutes (after a buzzer goes off) in order to keep the device on. This will eliminate the possibility of overheating due to the patient operator falling asleep.	The device treatment is intended to be self-administered in the home. The device is battery operated. It contains circuit boards that determine if the garment is making sufficient contact with the user, and if so, will output the designated power. The treatment time is based on the life of the battery, preventing the user from over treating.
Biocompatibility	Established	Established

Technical Specifications	Selicor Inc. Shortwave Diathermy System K020227	ViaTherm Therapeutics LLC ViaTherm BOOST Diathermy System K173300
Generator Technical Specifications:		
Operating Frequency	13.56 MHz	13.56 MHz
RF Power	8 to 40 watts	5 watts
Duty Cycle	Continuous Wave	Continuous Wave
RF Connector	BNC	BNC
Impedance	50 Ohms nominal	50 Ohms nominal
Load Standing Wave Ratio	1.6:1 max	3.0:1 max
Batteries	Rechargeable lead acid - 12V x 2 (24V), 4.5Ah	Ni-MH AA – 1.2V x4 (4.8V), 2000 mAh
Weight	9.6 lbs.	Approximately 26 oz.
Size	3.325" x 9.85" x 10.268"	2.25” x 4.875” x 6.5”
Sterility	Non-sterile	Non-sterile
Operating Temperatures	Operating: 32 to 122 degrees F (0 to 50 degrees C)	Operating: 59 to 104 degrees F (15 to 40 degrees C) at relative humidity of 30%-90% (non-condensing) and pressure of 700-1060 hPa.
Storage Temperatures	Storage: -4 to 140 F (-20 to 60 degrees C)	Storage: 50 to 140 degrees F (10 to 60 degrees C) at relative humidity of 15%-90% (noncondensing) and pressure of 700-1060 hPa.
Radiation Safety	Established	Established
RF Shielding	Yes	Yes
Designed to meet Electrical Safety Standards	IEC 60601-1	IEC 60601-1 IEC 60601-1-2 IEC 60606-1-6 IEC 60601-1-11
Coil design	Two helical coils embedded in a fabric garment	Two flat spiral coils embedded in a fabric garment

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Testing

Testing was performed to the following standards:

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances
- IEC 60601-1-6 Medical Electrical Equipment - General requirements for basic safety and essential performance - Usability
- IEC 60601-1-11 Medical Electrical Equipment - Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 62366 Medical Devices – Application of Usability Engineering to Medical Devices
- ISO 14971 Medical Devices – Application of Risk Management to Medical Devices

Temperature testing was performed in a muscle/bone phantom to assess the temperature rise in simulated tissue. A clinical test in nine healthy subjects was performed and the temperatures of tissue at the surface, 1cm and 2cm were measured.

Conclusion

The BOOST Diathermy System is as safe and effective as the predicate device. The BOOST Diathermy System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The BOOST Diathermy System is indicated for over-the-counter use, however, this modification in the indications for use and the labelling does not alter the therapeutic effect of the device. Usability testing demonstrated that the BOOST Diathermy System can be appropriately selected and used by the general population. The minor differences in design, size and shape to improve user interface between the BOOST Diathermy System and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the BOOST Diathermy System is as safe and effective as predicate device.

Based on the technical characteristics and the results of the performance testing, the BOOST Diathermy System is substantially equivalent to the predicate device.