January 27, 2023

Medispec Ltd.
Avner Spector
CEO
203 Perry Parkway, Suite 6
Gaithersburg, Maryland 20877

Re: K210166
Trade/Device Name: Omnispec ED1000
Regulation Number: 21 CFR 890.5660
Regulation Name: Therapeutic Massager
Regulatory Class: Class I
Product Code: ISA
Dated: November 16, 2022
Received: December 21, 2022

Dear Avner Spector:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210166

Device Name
Omnispec ED1000

Indications for Use *(Describe)*
The Omnispec ED1000 is intended for relief of minor muscle aches and pains, temporary increase in local blood circulation and activation of connective tissue.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
K210166

1. SPONSOR

Name:	Medispec, Ltd.
Address:	203 Perry Pkwy Ste 6 Gaithersburg, MD 20877
Phone:	1-240-552-7310
Fax:	301-972-6098
Contact Person:	Mr. Avner Spector
Email:	spector@medispec.com
Date Prepared:	July 12th, 2022

2. DEVICE INFORMATION

Proprietary Name:	Omnispec™ ED1000
Common Name:	Therapeutic Massager
Classification Name:	Massager, Therapeutic, Electric
Regulation Number:	21 CFR 890.5660
Product Code:	ISA
Device Class:	I

3. PREDICATE DEVICES

Equivalence is claimed to the OrthoGold 100™ of Tissue Regeneration Technologies, LLC, submissions number K210451, and D-ACTOR® 200 Vibration Massage System (K173692).

4. INTENDED USE

Omnispec™ ED1000TM is intended for the relief of minor muscle aches and pains, temporary increase in local blood circulation and activation of connective tissue.

5. DEVICE DESCRIPTION

Omnispec™ ED1000 is a portable, self-contained Shock Wave Therapy unit. It employs an electro-hydraulic method of creating shock waves. With this technique, an electrode, located within a water-containing stainless-steel reflector chamber called Shock Wave Applicator (SWA), ignites an electrical discharge, evaporating a small portion of the water and creating a shock wave reflecting outward off the reflector through a flexible membrane. The result is a shock (pressure) wave that passes through a conducting medium (patient). The shock wave is transmitted through the skin surface of the patient to the treatment site. The device provides focused pressure pulses where the second focus (F2) occurs within the membrane of the applicator. Treatment should only be applied to the upper extremities, from the shoulder to the wrist, and to the lower extremities from the hip to the foot.

6. PERFORMANCE TESTING

Verification and validation testing were performed and demonstrated that Omnispec™ ED1000 met the design specifications and it was safe and effective for its intended use. All tests required by the verification and validation plan were completed and passed successfully.

Omnispec™ ED1000's software was validated and demonstrated to be of a moderate level of concern . Hazard analysis / risk management was performed and demonstrated that all risks were mitigated to an acceptable level.

The skin contacting component of the Shock Wave Applicator was tested for biocompatibility and found to conform to elements of ISO 10993-1.

Omnispec™ ED1000 was tested and demonstrated to conform to the general safety requirements of ANSI AAMI ES60601-1, as well as the electromagnetic compatibility requirements of IEC 60601-1-2 and 60601-2-36.

Ultrasonic energy parameters were evaluated using protocols from IEC 61846. Those tests demonstrated that the energy output of Omnispec™ ED1000 was within the safe limits and was demonstrated to be equivalent to the predicate device.

In addition, pressure stability, acoustic noise, cleaning and disinfection, drop and vibration, as well as Shock Wave Applicator shelf life verification and validation tests was also conducted. The performance testing has

demonstrated that the Omnispec™ ED1000 is substantially equivalent to the predicate devices, and that it is safe and effective for its intended use. The table below compares Omnispec™ ED1000's characteristics to the predicate devices.

Description	OrthoGold 100™ (Main Predicate Device)	D-ACTOR® 200 (Predicate Device)	Omnispec™ ED1000 (Subject Device)	Comparison Notes
510(k) Number	K210451	K173692	K210166	NA
Product Code	ISA	ISA	ISA	Same
Regulation	21 CFR 890.5660	21 CFR 890.5660	21 CFR 890.5660	Same
Intended Use	Relief of minor muscle aches and pains, temporary increase in local blood circulation and activation of connective tissue	Relief of minor muscle aches and pains, temporary increase in local blood circulation and activation of connective tissue	Relief of minor muscle aches and pains, temporary increase in local blood circulation and activation of connective tissue	Same
Prescription/OTC use	Prescription	Prescription	Prescription	Same
Mode of Action	Unfocused pressure pulses	Radial (unfocused) pressure waves, or extracorporeal pulse activation respectively	Pressure pulses	Doesn't affect safety and effectiveness
Mechanism of Action	Extracorporeally induced unfocused pressure pulses	Pneumatically generated vibrations + unfocused pressure pulses	Extracorporeally induced pressure pulses	Similar
Shockwave Generation	Electrohydaulic, spark gap electrode	Pneumatic / ballistic	Electrohydaulic, spark gap electrode	Same / Similar, respectively
Coupling Solution	FDA-cleared ultrasound gel	FDA-cleared ultrasound gel	FDA-cleared ultrasound gel	Same
User Interface	Touch screen panel, touch wheel, foot	Specific description not available	Touch screen panel, hand-held applicator	Equivalent to OrthoGold 100™

Description	OrthoGold 100™ (Main Predicate Device)	D-ACTOR® 200 (Predicate Device)	Omnispec™ ED1000 (Subject Device)	Comparison Notes
	switch, hand-held applicator			
Main Unit Dimensions [mm]	218 x 400 x 459 (H x W x D)	Specific value not available	369 x 364 x 359 (H x W x D)	Similar to OrthoGold 100™, both suitable for desktop use
Shockwave Applicator Dimensions [mm]	230 x ø 70	4: 6mmOD, 15mmOD, 20mmOD, 35mmOD	130 x ø 90	Similar, all are intended to be hand-held
Pulses Frequency	Selectable, 1 - 8 Hz in steps of 0.5 Hz	Selectable, 1-21 Hz	Selectable, 2-2.5 Hz, 120 or 160 pulses/minute	Similar, Omnispec™ ED1000's frequencies are within the Predicates' range
Operating Mode	Continuous	Continuous	Continuous	Same as OrthoGold 100™
Peak compress-ional acoustic pressure pc [Mpa]	9.27 at energy level 16	18.5	13.8	Similar Omnispec™ ED1000's pressure is within the range of D-ACTOR® 200
Peak rarefactional acoustic pressure [Mpa]	-1.52 at energy level 16	6.8MPa at 5 bar	2.0	Similar Omnispec™ ED1000's pressure is within the range of D-ACTOR® 200
Positive peak pressure amplitude [Mpa]	0.43 - 9.27 at energy level 1 - 16	5 bar/18.5Mpa 3bar/13.4MPa	13.8	Similar Omnispec™ ED1000's pressure is

Description	OrthoGold 100™ (Main Predicate Device)	D-ACTOR® 200 (Predicate Device)	Omnispec™ ED1000 (Subject Device)	Comparison Notes
				within the range of D-ACTOR® 200
Distance between focus and target location	n/a	n/a	65mm	Doesn't affect safety and effectiveness
Maximum penetration depth (-6dB)	25.4mm at energy level 16	32 mm	110mm	Doesn't affect safety and effectiveness
Negative peak pressure amplitude (MPa)	-0.17 to -1.52 at energy level 1 - 16	5bar/6.8MPa 3bar/5.0MPa	2.0	Similar Omnispec™ ED1000's pressure is within the range of the predicates
Energy flow density	0.00017-0.04403mJ/mm2 at energy level 1-16	5bar/0.284mJ/mm2 3bar/0.176mJ/mm2	0.14 mJ/mm2	Similar Omnispec™ ED1000's energy flow density is within the range of the predicates
Derived focal acoustic pulse energy (mJ)	0.022 - 2.278 at energy level 1 - 16	5bar/6.5mJ 3bar/2.4mJ	1.035 at 14.5 kV	Similar, Omnispec™ ED1000's energy is within OrthoGold 100™'s range
Rise time (ns)	1.89 - 0.28 at energy level 1 - 16	Ultrasonic pulse: 2.5µs Sonic pulse: 25µs – 2.5ms	39	Similar Omnispec™ ED1000's rise time is within the range of D-

Description	OrthoGold 100™ (Main Predicate Device)	D-ACTOR® 200 (Predicate Device)	Omnispec™ ED1000 (Subject Device)	Comparison Notes
				ACTOR® 200
Compress-ional pulse duration (µs)	1.23 - 0.77 at energy level 1 - 16	Ultrasonic pulse: 5.0µs Sonic pulse: 50µs – 5.0ms	0.136	Similar
Applicator Wet Shelf Life	Specific Value Not Available	Specific Value Not Available	6 months	NA
Applicator Dry Shelf Life	Specific Value Not Available	Specific Value Not Available	18 months	NA
Applicator Use Life	100,000 pulses at energy level 1 – 10; 70,000 pulses at energy level 11 - 16	Specific Value Not Available	110,000 pulses	Similar, Omnispec™ ED1000 has only one energy level
Patient Contacting Materials	Membrane: Silicone Coupling Media: Ultrasound Gel	Coupling Media: Ultrasound Gel	Membrane: Silicone Coupling Media: Ultrasound Gel	Equivalent
Compliance with Consensus Standards	IEC 60601-1, IEC 60601-1-2, 60601-2-36, ISO 60601-1-6, ISO 62304, Draft IEC 63045, ISO 10993-1	IEC 60601-1, IEC 60601-1-2, ISO 62304, IEC 62304, IEC 61000-3-2, IEC 61000-3-3, ISO 10993-1	IEC 60601-1, IEC 60601-1-2, 60601-2-36, ISO 60601-1-6, ISO 62304, IEC 61846, ISO 10993-1	Equivalent, Draft IEC 63045 is equivalent to IEC 61846 but applies to unfocused pressure pulses

7. CLINICAL TESTING

Not applicable

8. SUMMARY

Omnispec™ ED1000 has the same intended use and similar design features as compared with the predicate systems. The devices share similar core technologies and principle of operation. The performance testing has demonstrated that the performance characteristics of Omnispec™ ED1000 are equivalent to those of other legally marketed therapeutic massagers, and

therefore it supports a determination of Substantial Equivalence for the proposed intended use.

Any differences between Omnispec™ ED1000 and the predicate device do not affect the safety or effectiveness, or raise different questions of safety and effectiveness.