May 5, 2025

ZAMAR Medical d.o.o.
% Guido Bonapace
Official Correspondent
Isemed Srl
Via P. Togliatti, 19/X
Imola (BO), 40026
Italy

Re: K242754
Trade/Device Name: ZT Clinic (MG675A); ZT Cube (ZC3) (MG465A); Z-ONE (MG455A)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, ILO
Dated: January 27, 2025
Received: January 28, 2025

Dear Guido Bonapace:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Julia E. Slocomb -S 2025.05.05 11:30:42 -04'00'

for Heather Dean, PhD
Assistant Director
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K242754

Please provide the device trade name(s).

ZT Clinic (MG675A);
ZT Cube (ZC3) (MG465A);
Z-ONE (MG455A)

Please provide your Indications for Use below.

The Heat Exchange Equipment for Cryotherapy and Thermotherapy provides a combination of cold, heat, contrast, and compression therapies.
It is intended to treat post-surgical and trauma injuries to reduce edema, swelling and pain, for which cold and compression are indicated.
It is intended to treat post traumatic and post-surgical medical and/or surgical conditions, for which localized thermal therapy (hot or cold or contrast) are indicated.
The equipment is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, and athletic training settings.

Please select the types of uses (select one or both, as applicable).

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

General Information

Applicant: ZAMAR Medical d.o.o.
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Date prepared: 4th April 2025

Device Name
Device Trade Name: Z-ONE, ZT Cube (ZC3), ZT Clinic
Common Name: Powered inflatable tube massager
Classification name: Massager, Powered Inflatable Tube
Regulation Number: 890.5650
Product Code: IRP, ILO

Legally Marketed Predicate Devices

510(k) Number	Predicate Trade Name	Product code
K171685	Game Ready Med4 Elite™	IRP, ILO

Device Description

The Heat Exchange Equipment for Cryotherapy and Thermotherapy (Z-ONE, ZT Cube and ZT Clinic) are AC-powered, software-controlled multi-modality devices, designed to impart localized heat exchange and compression therapies. The devices have been developed with the possibility of choosing between different programs: cold therapy, heat therapy and contrast therapy (alternating hot and cold). Moreover, they also possess an intermittent pneumatic compression activity, which is the effect of an alternance of compression and decompression. The compression activity is available in four different levels: minimum (15 mmHg), low-medium (40 mmHg), medium (60 mmHg) and maximum (80 mmHg). It is also possible for the professional user to select the duration of the pulsed compression. With heat treatment, only a low compression level, i.e. 15 mmHg can be selected.
The device allows for a maximum treatment time of 30 minutes for heat therapy, 90 minutes for cold therapy, and 90 minutes for contrast therapy.

The devices are designed to be compatible with a series of Thermal Wraps, that are available for different parts of the body: full leg, shoulder, thigh, knee, calf, elbow, wrist, ankle and hip.

The devices are designed to be used in rehabilitation facilities, outpatient clinics, and athletic training settings, by, or on the order of, licensed health care professionals.
The Heat Exchange Equipment for Cryotherapy and Thermotherapy is available in 3 different models:
• Z-ONE: portable unit with a comfortable handle for moving. This model is developed to deliver only cold therapy, with a temperature range between 41°F and 59°F (5°C - 15°C) and it allows the connection of up to two wraps at the same time and therefore the possibility to treat more patients using the same program simultaneously.
• ZT Cube: portable unit with a comfortable handle for moving. This model allows the delivery of cold therapy, heat therapy and contrast therapy (alternating hot and cold), with a temperature range of 34°F as minimum and 104°F as maximum (1°C - 40°C). Up to two wraps can be connected at the same time.
• ZT Clinic: unit designed and built for the complex needs of clinics and hospitals, as it can suit up to 4 thermal wraps simultaneously. This model can be used to deliver cold therapy, heat therapy and contrast therapy, alternating hot and cold. Temperature range is 34°F as minimum and 113°F as maximum (1°C - 45°C).
The devices are controlled by an intuitive touch screen computer interface, allowing the user to manage the therapy modalities as well as easily adjust and monitor treatment times, temperature and compression settings.

Intended use / Indications for Use

The Heat Exchange Equipment for Cryotherapy and Thermotherapy provides a combination of cold, heat, contrast, and compression therapies.
It is intended to treat post-surgical and trauma injuries to reduce edema, swelling and pain, for which cold and compression are indicated.
It is intended to treat post traumatic and post-surgical medical and/or surgical conditions, for which localized thermal therapy (hot or cold or contrast) are indicated.
The equipment is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, and athletic training settings.

Substantial equivalence comparison

In the table below a detailed comparison of the subject devices Heat Exchange Equipment for Cryotherapy and Thermotherapy (Z-ONE, ZT Cube, ZT Clinic) and predicate device Med4 Elite™ is provided.

Characteristic	**Proposed Device**	**Main Predicate**	**Comparison**
	Z-ONE, ZT Cube, ZT Clinic	**Game Ready® Med4 Elite™**	
Manufacturer	ZAMAR Medical D.o.o	CoolSystems® (dba Game Ready)	
Classification Name	Powered inflatable tube massager	Powered inflatable tube massager	Substantially equivalent.
Classification Product Code	IRP	IRP	Substantially equivalent.
Subsequent Product Code	ILO	ILO	Substantially equivalent.

Intended use			
Indications for use	The Heat Exchange Equipment for Cryotherapy and Thermotherapy provides a combination of cold, heat, contrast, and compression therapies. It is intended to treat post-surgical and trauma injuries to reduce edema, swelling and pain, for which cold and compression are indicated. It is intended to treat post traumatic and post-surgical medical and/or surgical conditions, for which localized thermal therapy (hot or cold or contrast) are indicated. The equipment is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, and athletic training settings.	The Med4 Elite™ combines cold, heat, contrast and compression therapies. It is intended to treat post-surgical and acute injuries to reduce edema, swelling and pain for which cold and compression are indicated. It is intended to treat post traumatic and postsurgical medical and/or surgical conditions for which localized thermal therapy (hot or cold or contrast) are indicated. It is intended to be used by or on the order of licensed healthcare professionals in rehabilitation facilities, outpatient clinics and athletic training settings.	Subject device, the Heat Exchange Equipment for Cryotherapy and Thermotherapy, has the same indications for use and intended users of the primary predicate device Med4 Elite™. The devices are substantially equivalent.
Intended Users	Health Care Professionals only (Prescription use)	Health Care Professionals only (Prescription use)	All devices are prescription use only. Subject devices and primary predicate Med4 Elite™ can only be used by health care professionals. The devices are substantially equivalent.
Where used (hospital, home, ambulance, etc)	Intended for indoor use only such as rehabilitation clinics, outpatient clinic, athletic training settings.	Intended for indoor use only such as rehabilitation clinics, outpatient clinic, athletic training settings.	Substantially equivalent to primary predicate: intended to be used in the same places.
Number of Patients that can be treated	Two patients with single locations or two anatomical locations on one patient. 4 possible connections with ZT Clinic.	Two patients with single locations or two anatomical locations on one patient.	Subject devices and primary predicate allow for the connection of 2 applied parts at the same time. ZT Clinic model can accommodate the connection of up to 4 different applied parts, but this difference does not raise new safety or effectiveness questions, since the treatments are always managed and controlled by a professional user.
Physical unit			
Energy used and/or delivered	AC powered	AC powered	Substantially equivalent to primary predicate.
User Interface	Display touchscreen Z-ONE: 5'' ZT Cube: 7'' ZT Clinic: 10,4''	Display touchscreen	Substantially equivalent to primary predicate.
Design	Z-ONE: portable unit, equipped with a handle for moving. ZT Cube: portable unit, equipped with a handle for moving. ZT Clinic: wheeled model, with brakes.	Wheeled unit, with brakes.	Subject device ZT Clinic is substantially equivalent to primary predicate. Z-ONE and ZT Cube are portable units, however this difference does not raise additional concerns regarding the safety and effectiveness of the devices.
Dimensions	Z-ONE: 11" x 10" x 12"H ZT Cube: 15" x 12" x 13"H	32.5" L x 24.75" W x 43"H	Subject devices are smaller than primary predicate.

	ZT Clinic: 15” x 22” x 37”H		
Weight empty	Z-ONE: 20 lbs (9kg) ZT Cube: 31 lbs (14kg) ZT Clinic: 95 lbs (43kg)	172 lbs (78 kg)	Subject devices are lighter than primary predicate.
Weight fully loaded	Z-ONE: 26 lbs (12kg) ZT Cube: 37 lbs (17kg) ZT Clinic: 106 lbs (48kg)	188 lbs (85kg)	Subject devices are lighter than primary predicate.
Chilling Mechanism	Combination of a refrigeration system with a hydraulic system.	Vapor compression	Different chilling mechanisms, but they all accomplish the generation of cold, without safety impacts.
Heating Mechanism	Combination of a refrigeration system (with the aid of 4-way valve to force the reverse cycle) with a hydraulic system.	Resistance heaters	Different heating mechanisms, however this difference does not raise questions of safety or effectiveness.
Reservoir Fluid Capacity	Single reservoir of about one liter	Heat reservoir: 1 gallon (3.8 L) Cold reservoir: 1 gallon (3.8 L)	Subject devices have a single reservoir for heat and cold, while primary predicate have got 2 separated reservoirs for heat and cold. This difference does not have an impact on devices safety.
Recommended Coolant	NON-TOX Cooling glycol	Distilled Water	The coolant is different between subject devices and predicate device, but each device is able to attain its desired performance requirements and there is no safety impact from this difference.
Functions			
Heat Therapy	Available within the specific temperature ranges of the models, either without compression or with low compression. Z-ONE: only cold therapy	Available without and with compression (Low only).	The subject devices (excluding Z-ONE) provide the option to deliver heat therapy either without compression or with low compression. The primary predicate also allows for the selection of low or no compression during heat therapy delivery. The subject devices are substantially equivalent to the primary predicate device.
Heat Therapy Treatment time	5 to 30 minutes.	5 to 30 minutes Default setting: 15 minutes	The treatment time for the subject devices can be adjusted between 5 and 30 minutes for heat therapy. The primary predicate features a default setting of 15 minutes for heat treatment, with the option to adjust the duration within the same range of 5 to 30 minutes. The subject devices are substantially equivalent to the primary predicate.

Cold Therapy	Available without and with compression in 4 levels (Low, Medium-low, Medium, High)	Available without and with compression (Low, Medium-low, Medium, High)	Subject devices are substantially equivalent to predicate device.
Cold Therapy Treatment Time	5 to 90 minutes.	5 to 60 minutes Default setting: 15 minutes	The treatment time for the subject devices can be adjusted in one-minute increments, ranging from 5 to 90 minutes. The primary predicate has a default setting of 15 minutes, with the option to adjust the duration from 5 to 60 minutes. For the evaluation of this specific characteristic, the device Game Ready GRPro 2.1 System (K192114) has been also considered, which features a default setting of 15 minutes and allows treatment times to be adjusted from 5 to 90 minutes in 5-minute increments. As a result, this device shares the same characteristics of subject devices. No additional safety concerns arise.
Contrast Therapy	Available for ZT Cube and ZT Clinic. Treatment cycles of Cryotherapy, Thermotherapy, Pause and Repeat can be individually set. Treatment up to 90 minutes. Not available for Z-ONE.	Available Heat: 1 – 10 minutes, default 3 minutes Cold: 1 – 10 minutes, default 3 minutes Total treatment 15 – 90 minutes, default 30 minutes	Contrast therapy is available both for subject devices (ZT Cube and ZT Clinic) and for primary predicate device. Both offer the possibility of setting treatment cycles (thermotherapy, cold therapy, pause and repeat), which are under the control of a clinician. Treatment time is up to 90 minutes for both subject devices and primary predicate. The devices are substantially equivalent.
Compression range	Available in four levels Low: 15 mmHg Medium-low: 40 mmHg Medium: 60 mmHg High: 80 mmHg Possibility of selecting compression time applied to the treated part, intermittent compression.	Available in four levels Low (5 – 15 mm Hg) Medium-Low (5 – 30 mm Hg) Medium (5 -50 mm Hg) High (5 -75 mm Hg)	Compression therapy is available for subject devices and predicate device. The subject devices offer four levels of compression: low (15 mmHg), medium-low (40 mmHg), medium (60 mmHg), and high (80 mmHg). The primary predicate also provides four compression levels. No additional safety concerns arise.
Temperature range	Z-ONE: 41°F - 59°F ZT Cube: 34°F - 104°F ZT Clinic: 34°F – 113°F	Heat reservoir: 95° - 113° F Cold reservoir: 38° - 50° F	The maximum temperature, corresponding to 113°F, is identical to that of the primary predicate device. As regard to the lowest temperature that can be reached for the cryotherapy treatment, also the Game Ready GRPro 2.1 System

			(K192114) has been considered. This device reaches a temperature of 33.8°F, which is lower than the minimum temperature that can be achieved by the subject devices. No additional safety concerns arise.
Software features	Electronic pressure control and therapy time and temperature monitoring.	Electronic pressure control and therapy time and temperature monitoring.	Substantially equivalent to primary predicate device.
Electrical characteristic			
Line Voltage	115V	100-240 VAC	No safety impact from this difference. All have been tested for electrical safety.
Line Frequency	60 Hz	50/60 Hz	Substantially equivalent.
Electrical Safety Standards	• IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION • ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] • IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Type BF	ANSI/AAMI ES60601-1:2005/(R) 2012 CAN/CSA C22.2 No. 60601- 1:2014 Type B	Substantially equivalent to predicate device.
Environmental characteristics			
Operating Temperature	50°F - 86°F (10°C – 30°C)	50°F - 90°F (10°C – 32°C)	Similar but not equal operating temperatures. No safety or effectiveness concerns regarding this difference.
Storage Temperature	50°F - 104°F (10°C – 40°C)	33° - 122°F (1° - 50°C)	Similar but not equal storage temperatures. No safety or effectiveness concerns regarding this difference.
Operating Humidity	Relative humidity 10% - 50%	30 to 90%, Non-condensing	Different operating humidity, however this difference does not impact safety of subject devices.
Storage Humidity	Relative humidity 30%-60%	10 to 95%, Non-condensing	Different storage humidity, however this difference does not impact safety of subject devices.
Operating Atmospheric Pressure	0 – 6,500 Ft (0 – 2,000 m)	0-9,843 Ft (3,000 meters)	Subject devices are characterized by a smaller operating atmospheric pressure, however it is more than adequate for an indoor use.
Expected lifetime	5 years	5 years	Substantially equivalent.
Wraps			
Types of Wraps	The wraps are available for different parts of the body: full leg, shoulder, thigh, knee calf, lumbar, elbow wrist, ankle, knee, hip.	Various anatomical Wraps in different sizes for: Straight Knee, Articulated Knee, Elbow, Ankle, Shoulder, Back, Hip- Groin, Hand-Wrist, Flexed Elbow, Half-leg boot.	Subject devices available wraps overlap body parts covered by predicate device's wraps.
Wrap Technology	Flexible wraps, formed by two separated chambers: one for the	Flexible Wraps; outer sleeve with inner heat exchanger to deliver	Substantially equivalent, both devices are

	compression activity and one with a coil allowing the passage of the NON TOX liquid.	compression and cold. 2-chamber heat exchanger (water and air).	characterized by a chamber for compression and a chamber for heat/cold.
Patient Contacting Material	Polyether Polyurethane	70 Denier nylon	The patient contacting material of ZAMAR thermal wraps is Polyether Polyurethane, which is different from the material used for wraps of primary predicate device. However, this material has been approved for skin patient contact and tested for biocompatibility.
Biocompatibility	ISO 10993-1:2018 ISO 10993-12:2021 ISO 10993-5:2009 ISO 10993-10:2021 ISO 10993-23:2021	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-12	Patient contacting material has been tested for cytotoxicity according to ISO 10993-5, skin sensitization according to ISO 10993-10 and intracutaneous reactivity according to ISO 10993-23. Moreover, a declaration of the manufacturer of material reports the conformity to FDA, conformity to RoHS and suitability for skin contact as the material is conform to the USP class VI. Subject device has been tested for the same tests of primary predicate device and therefore there are not safety or effectiveness concerns.
Sterility	Provided non-sterile only	Provided non-sterile only	Substantially equivalent.
Expected lifetime of accessories	1 years or 200 applications	3 – 24 months, depending on use	Expected lifetime of thermal wraps of subject devices is shorter than thermal wraps available for predicate devices. However, this difference does not raise safety concerns.

The rationale for the substantial equivalence of subject devices and predicate device is based on the same technical principles of providing cold or heat therapy combined with compression therapy.
In light of evidence reported in the comparison table and based on classification, intended use, general technological characteristics, specific features and applied parts, it can be concluded that the subject device (the Heat Exchange Equipment for Cryotherapy and Thermotherapy) is as safe and effective as the primary Med4 Elite™.
In particular, as regard to technological characteristics, performance bench tests performed on subject devices demonstrated their ability to function according to predetermined specifications. The temperature range of ZAMAR devices aligns the maximum heat therapy temperature of the Med4 Elite™ device.
Regarding the lowest temperature range and the cryotherapy treatment time, subject devices have similar characteristics to that of the medical device Game Ready GRPro 2.1 System (K192114). Consequently, this device has been referenced for these specific characteristics.

None of the performance or technological differences between subject and predicate devices raises new issues of safety and effectiveness. The rationale for the substantial equivalence of subject and predicate device is based on the same technical principles of providing cold or heat therapy combined with compression therapy. Patient contacting material is different, however ZAMAR thermal wraps have been evaluated according to ISO 10993-1, and no new safety and effectiveness concerns were found.
In conclusion, any differences between the subject devices and the predicate devices do not raise new issues of safety and effectiveness. The subject device Z-ONE, ZT Cube and ZT Clinic are as safe, as effective, and perform comparably to predicate device for the same intended use.

Non- Clinical and/or Clinical Tests Summary & Conclusions

Performance of the Heat Exchange Equipment for Cryotherapy and Thermotherapy devices (Z-ONE, ZT Cube and ZT Clinic) have been evaluated and tested by performing a leakage test from the tank and a temperature test to verify the capacity of the thermal wraps to reaching the desired and set temperature. In addition, to verify the device's functional properties, the following performance tests were performed:
- Temperature accuracy
- Pressure accuracy
- Wrap seam strength

Results of the tests indicated that the devices conform to theirs predetermined specifications and operate within safety limits.
Furthermore, as required by the "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices" (July 26, 1995), reformatted 12/18/97, the devices were tested for skin temperatures in the worst-case use scenario on healthy volunteers who provided informed consents.
The durability of the thermal wraps has been tested under simulated real-use conditions, demonstrating the device's ability to maintain its integrity and performance over 200 repeated application cycles.

In conclusion, the testing data validates that the subject devices perform as intended under their proposed use conditions. The Heat Exchange Equipment for Cryotherapy and Thermotherapy (Z-ONE, ZT Cube, and ZT Clinic) meets all safety and performance requirements, confirming substantial equivalence to the predicate device in terms of indications for use and technological characteristics.