May 15, 2025

EYWA srl
% Thomas Lawson
Regulatory Affairs for EYWA srl
EYWA srl America
1224 Navellier Street
El Cerrito, California 94530

Re: K243165
Trade/Device Name: Limfa Therapy System (Limfa Therapy)
Regulatory Class: Class II
Product Code: NGX
Dated: September 26, 2024
Received: September 30, 2024

Dear Thomas Lawson:

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,

Tushar Bansal -S

for 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243165

Device Name

Limfa Therapy System (Limfa Therapy)

Indications for Use *(Describe)*

The indications for the Limfa Therapy System are to temporarily increase blood circulation in healthy leg muscles and to stimulate healthy muscles in order to improve and facilitate muscle performance.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

General Information

Submitter	Eywa S.r.l.
Address	Eywa S.r.l. Via Pietrarubbia, 25/E Rimini 47922 Italy
510(k) Number	K243165
Correspondence Person	Thomas Lawson, PhD
Contact Information	Email: drthomlawson@gmail.com Phone: 510-206-1794
Date Prepared	14 May 2025

Proposed Device

Trade Name	Limfa® Therapy System
Common Name	Limfa® System
Regulation Number and Regulation Name	21 CFR§890.5850. Powered Muscle Stimulator
Product Code	NGX
Regulatory Class	II

Predicate Device #1

Trade Name	Bemer Classic Set
Common Name	Bemer Classic

Premarket Notification	K151834
Regulation Number and Classification Name	21 CFR§890.5850, Powered Muscle Stimulator
Product Code	NGX
Regulatory Class	II

Predicate Device #2

Trade Name	Bemer Classic Set
Common Name	Bemer Classic
Premarket Notification	K210174
Regulation Number and Regulation Name	21 CFR§890.5850. Powered Muscle Stimulator
Product Code	NGX
Regulatory Class	II

Device Description

The Limfa® Therapy System is a medical device, intended for stimulation with extremely low frequencies (ELF), pulsed, and low frequency (ELF 3-300 Hz) magnetic fields, which generates pulsed, bipolar and variable electromagnetic fields, at very low and variable intensity and frequency using complex waveforms (sinusoidal, triangular and rectangular), thus obtaining multiple signals within a frequency spectrum composed of base waves from 2 to 80 Hz plus the harmonics that are produced by the hardware component.

The manufacturer presets base wave frequencies and the harmonics are generated by the DM hardware. The therapy is based on the generation of a pulsed magnetic field with a very low and variable frequency and variable intensity.

Indications for Use

The indications for use of the Limfa® Therapy System are:

- To temporarily increase local blood circulation in healthy leg muscles;
- To stimulate healthy muscles in order to improve and facilitate muscle performance;

The Limfa® Therapy System has the exact same intended use and indications for use

statements as the BEMER Classic Set device.

Comparison of Technological Characteristics with the Predicate Devices

The Limfa® Therapy System is equivalent to two predicate devices in terms of indications for use, intended use, and a basic design in which the user places an emitter focused on the target body region (predicate device #K151834) or the patient lies on a body pad (predicate device #K210174) in order to facilitate electrical stimulation of affected body parts. All three devices meet EM compatibility and electrical safety standards. In general, these three devices are substantially equivalent since they share basic designs and are used repeatedly in order to achieve the desired clinical effect.

Comparison of the LIMFA Therapy System's Emitter (subject device) to the BEMER Classic Set's B.SPOT Emitter

	Subject Device LIMFA Therapy System's Emitter Eywa S.r.l. (This Submission)	Predicate Device #1 BEMER Classic Set's B.SPOT BEMER Int. AG (K151834)	Equivalence
Class	II	II	Equivalent The class is the same
Product Code	NGX	NGX	Equivalent The product code is the same
Regulation	21 CFR 890.5850	21 CFR 890.5850	Equivalent The regulation is the same

Indications for Use	To temporarily increase local blood circulation in healthy leg muscles. To stimulate healthy muscles in order to improve and facilitate muscle performance	To temporarily increase local blood circulation in healthy leg muscles. To stimulate healthy muscles in order to improve and facilitate muscle performance	The statements are the same Devices are equivalent
Site of use	Hospitals, physician offices and home	Same	Sites of use are the same Devices are equivalent
System Components	1. Control unit (console) 2. Emitters (max. 2 emitters connected to a console) 3. AC/DC power adapter	1. B.Box Classic Control unit (console) 2. B.SPOT (max 2 emitters connected to a console) 3. AC/DC power adapter	Equivalent The systems have comparable components
Technical Characteristics			
Primary Mode of Action	Non-invasive tissue stimulation via magnetic field induction	Same	The primary mode of action is the same. Devices are equivalent
Waveform	Pulsed asymmetric, variable amplitude during treatment	Pulsed asymmetric, constant amplitude during treatment	Equivalent The Limfa Therapy System delivers different frequencies by modulating both the waveform type and the pulse amplitude, allowing the system to

			generate complex therapeutic signals using multiple waveform shapes. In contrast, the predicate device (Bemer) achieves frequency variation by adjusting the duration of a fixed waveform—specifically a sinusoidal pulse—while keeping amplitude relatively constant. Therefore, while the predicate device is limited to sine wave modulation with variable pulse widths, the Limfa system achieves comparable therapeutic frequencies using a broader range of waveform dynamics, including controlled variation in amplitude. Despite these differences in signal construction, both systems remain within comparable frequency and intensity ranges, supporting substantial equivalence.
Wave Shape	Variable, bipolar	Sinusoidal, monopolar	Equivalent While the predicate device utilizes a monopolar sinusoidal waveform, Limfa employs a variable, bipolar waveform, which allows for more flexible signal shaping and improved field symmetry. Bipolar waveforms are widely used in PEMF literature and are considered advantageous for reducing net charge accumulation in tissues and for enhancing waveform balance and reproducibility. Despite this difference, both systems deliver low-frequency pulsed electromagnetic stimulation within comparable intensity ranges, achieving the same therapeutic objective.
Pulse repetition rate	2 – 80 Hz	10 – 30 Hz	Both devices operate within the Extremely Low Frequency (ELF) range (typically defined as 0–100 Hz). The Limfa Therapy System uses frequencies between 2–80 Hz, while the predicate device operates between

			10–30 Hz. These frequency ranges overlap, and both fall well within the established therapeutic ELF window used in PEMF therapy. Therefore, despite Limfa offering a broader frequency range, the core therapeutic frequencies are comparable, supporting substantial equivalence.
Single pulse duration	Fixed 1 μS	10 – 33 μS	The Limfa Therapy System and the Bemer device deliver PEMF signals using different waveform generation methods, but achieve the same therapeutic goal. Limfa uses ultra-short bipolar pulses (1 μs) at a carrier frequency of 100 kHz, modulated at therapeutic frequencies (e.g., 10 Hz). This approach enables precise shaping of the waveform and minimizes tissue polarization. In contrast, the Bemer system applies monopolar sinusoidal pulses directly at 10–30 Hz, with frequency modulation achieved through varying the pulse width. The waveform comparison (see figure) shows that while the carrier and waveform structures differ, both systems deliver comparable low-frequency electromagnetic stimulation in the ELF range (0–100 Hz), and thus remain substantially equivalent in safety and intended therapeutic effect.
Average Flux Density	Up to 190 μT	Up to 100 μT	Equivalent The subject device has a higher average flux density compared to the predicate device. However, this difference does not impact safety and effectiveness. The slightly higher value for the subject device remains within the safe exposure limits defined by ICNIRP and IEC 60601 standards for low-frequency magnetic fields.

Maximum output voltage	N/A	N/A	Equivalent
Maximum Output Current	Current directly applied to the patient's body <5mA (acc. to IEC 60601-1)	Current directly applied to the patient's body <5mA (acc. to IEC 60601-1)	Equivalent Using the same technology to apply the current in the form of indirect induction through an electromagnetic field Both devices use the same safety standard (IEC 60601-1) and the same equivalent frequency to induce a similar quantity of current into the body to result in equivalent effectiveness.
Treatment mode, Treatment time			
Local Treatment	Local Applicator Max 2 applicators connected to console Local treatment on skeletal muscles—to be used in separate locations (not at the	Same Same	Equivalent Equivalent

	same time) Treatment area restricted by applicator geometry Intensities 1 – 7 1-7 Programs Intensities Preset according to the program selected Treatment time 20 to 53 minutes. Stimulation per treatment is performed in intervals: 20 minutes of stimulation is followed directly by 10 minutes of no stimulation.	Same Intensities 1 – 10 Treatment time 8 minutes Intensities 3 – 10 Treatment time 8 to 20 minutes	Equivalent Equivalent Equivalent While the Limfa Therapy System offers a timer range of 20 to 53 minutes, compared to 8 to 20 minutes in the predicate device, this extended duration does not represent a significant change in clinical application or safety profile. Both devices operate within comparable frequency and intensity parameters. The additional time in Limfa simply allows for extended application when using lower duty cycles, without increasing the electromagnetic dose beyond what is already documented as safe and effective. Limfa's standard protocol is 1 treatment (20 to 53 minutes), 3 times a week, while the predicate device is recommended for daily use. Limfa's treatment stimulation is performed in intervals: 20 minutes of stimulation is followed directly by 10 minutes of no stimulation. Therefore, the increased timer flexibility does not alter the intended use or impact safety and effectiveness, and the two systems remain substantially equivalent in their therapeutic range.

Weight of the console	3.5 kg	1.3 kg	Equivalent The difference is due to the fact that the LIMFA system has a passive heatsink cooling system that discharges onto the metal casing while the predicate devices have fan cooling and a plastic casing. This weight difference does not affect the usability or portability of the subject device in relation to that of the predicate devices.
Dimensions of the console	34 x 19 x 6 cm	32 x 32 x 7 cm	Equivalent The small difference in dimensions of the consoles does not affect safety or effectiveness.
Dimensions of the Emitters	11.7 x 6.3 x 2.7 cm	13 x 13 x 3 cm	Equivalent The modest dimensional differences are due to the orientation of the coils contained within the Emitters. The subject device's Emitter contains vertical coils in an oblong capsule with rounded edges. This shape concentrates the magnetic field over a narrow rectangular patch while keeping the Emitter thin, lightweight, and easy to strap in place at localized treatment areas. The Emitter of the predicate device has a horizontal coil that is contained in a circular, disc-like housing. Bench testing confirms that both Emitters deliver equivalent ranges of average flux density; consequently, the shape and size differences do not raise new safety or effectiveness concerns.
Power consumption	36 Watt max	30 Watt max	Equivalent The extra 6 watts of the subject device does not affect safety or effectiveness
Input	90-264 VAC 47-63 Hz 0.25 – 0.74 A	100-240 VAC 50-60 Hz 0.6 A	Equivalent
Output	12 VDC 0 – 5 A	12-15.1 Vdc 2.0 A	Equivalent

Biocompatibility	Yes	Yes	Equivalent
Number of output modes	1	1	Equivalent
Number of output channels and ports	2	2 for each	Equivalent
Software Controlled	Yes	Yes	Equivalent

Voltage / Current Level	1-7 programs using variable intensity	1-10 intensity indicator	Equivalent
Timer Range	20 to 53 minutes	8 to 20 minutes	Equivalent The extended duration of the subject device does not represent a significant change in clinical application or safety profile. Both devices operate within comparable frequency and intensity parameters. The additional time in Limfa simply allows for extended application when using lower duty cycles, without increasing the electromagnetic dose beyond what is already documented as safe and effective. Limfa's treatment stimulation is performed in intervals: 20 minutes of stimulation is followed directly by 10 minutes of no stimulation. Therefore, the increased timer flexibility does not alter the intended use or raise new questions of safety or effectiveness, and the two systems remain substantially equivalent in their therapeutic range.
Compliance with voluntary standards	EN 60601-1 EN 60601-1-2 EN 60601-1-6 EN 62366	IEC 60601-1 IEC 60601-1-2 EN 60601-1-6	Equivalent

	EN 62304 EN 62353 IEC TR 60601-4-2 EN ISO 14971 EN ISO 15223-1	EN 62366 EN 60601-1-11	

Sterilization	Not provided sterile	Not provided sterile	Equivalent

Comparison of the Limfa Therapy System's Body Mat (subject device) to the BEMER Classic B.Body Mat (predicate device #2).

	Subject Device Limfa Therapy System Eywa S.r.l. Body Mat (This Submission)	Predicate Device #2 BEMER Classic Set's B.BODY. BEMER Int. AG (K210174)	Equivalence
Class	II	II	Equivalent The class is the same
Product Code	NGX	NGX	Equivalent The product code is the same
Regulation	21 CFR 890.5850	21 CFR 890.5850	Equivalent The regulation is the same

Indications for Use	To temporarily increase local blood circulation in healthy leg muscles. To stimulate healthy muscles in order to improve and facilitate muscle performance	To temporarily increase local blood circulation in healthy leg muscles. To stimulate healthy muscles in order to improve and facilitate muscle performance	Equivalent The statements are the same
Site of use	Hospitals, physician offices and home	Same	Sites of use are the same Devices are equivalent

System Components	1. Control unit (console) 2. Total Body Mat (max. 2 mats connected to the console) AC/DC power adapter	1. B.Box Classic Control unit (console) 2. B.BODY pad (max. 2 pads connected to the console) AC/DC power adapter	Equivalent The systems all have comparable components

Primary Mode of Action	Non-invasive tissue stimulation via magnetic field induction	Non-invasive tissue stimulation via magnetic field induction	Equivalent The primary mode of action is the same.
Treatment of large or multiple regions simultaneously	Yes	Yes	Equivalent The treatments actions are the same.
Local Treatment	Local Applicator 1 Body Mat connected to console Local treatment on skeletal muscles Treatment area restricted by applicator geometry 1-7 Programs Intensities Preset according to the program selected Treatment time 20 to 53 minutes. Stimulation per treatment is performed in intervals: 20 minutes of stimulation is followed directly by 10 minutes of no stimulation.	Local Applicator (max 2 body pads) connected to console Same Same Intensities 1 – 6 Treatment time 8 mins Intensities 1 – 10 Treatment time 8 to 20 minutes	Equivalent Equivalent Equivalent Equivalent While the Limfa Therapy System offers a timer range of 20 to 53 minutes, compared to 8 to 20 minutes in the predicate device, this extended duration does not represent a significant change.

			Both devices operate within comparable frequency and intensity parameters. The additional time in Limfa simply allows for extended application when using lower duty cycles, without increasing the electromagnetic dose beyond what is already documented as safe and effective. Limfa's standard protocol is 1 treatment (20 to 53 minutes) 3 times a week, while the predicate device is recommended for daily use. Limfa's treatment stimulation is performed in intervals: 20 minutes of stimulation is followed directly by 10 minutes of no stimulation. Therefore, the increased timer flexibility does not alter the intended use or impact safety and effectiveness. The two systems remain substantially equivalent in their therapeutic range.
Weight of the console	3.5 kg	1.3 kg	Equivalent The difference is due to the fact that the LIMFA system has a passive heatsink cooling system that discharges onto the metal casing while the predicate devices have fan cooling and a plastic casing. This weight difference does not affect the usability or portability of the subject device in relation to that of the predicate devices.
Dimensions of the console	34 x 19 x 6 cm	32 x 32 x 7 cm	Equivalent The small difference in dimensions of the consoles does not affect safety or effectiveness.

Dimensions of the full body mat	170 x 75 x 2.2 cm	180 x 60 x 2 cm	Equivalent The dimensional difference of the two mats/pads do not affect safety or effectiveness of the two devices.
Average Flux Density	Up to 35.5 µT	Up to35 µT (max level)	Equivalent The subject device has an Average Flux Density that is similar to that of the predicate device. Therefore, this does not impact safety and effectiveness.
Power consumption	36 Watt max	30 Watt max	Equivalent The extra 6 watts of the subject devices, required by the larger display, do not affect safety or effectiveness
Input	90-264 VAC 47-63 Hz 0.25 – 0.74 A	100-240 VAC 50-60 Hz 0.6 A	Equivalent
Output	12 VDC 0 – 5A	12-15.1 Vdc 2.0 A	Equivalent
Biocompatible	Yes	Yes	Equivalent
Number of output modes	1	1	Equivalent
Number of output channels and ports	2	2	Equivalent
Software controlled	Yes	Yes	Equivalent
Voltage / Current Level	1-7 programs using variable intensity	1-10 intensity indicator	Equivalent The intensity is related to the program the user chooses for applying the magnetic field.

Timer Range	20 to 53 minutes	8 to 20 minutes	Equivalent The extended duration of the subject device does not represent a significant change in clinical application or safety profile. Both devices operate within comparable frequency and intensity parameters. The additional time in Limfa simply allows for extended application when using lower duty cycles (Limfa suggested duty cycle is 3 times a week, while the predicate device is recommended for daily use), without increasing the electromagnetic dose beyond what is already documented as safe and effective. Limfa's treatment stimulation is performed in intervals: 20 minutes of stimulation is followed directly by 10 minutes of no stimulation. Therefore, the increased timer flexibility does not alter the intended use or impact safety and effectiveness. The two systems remain substantially equivalent in their therapeutic range.

Compliance with voluntary standards	EN 60601-1 EN 60601-1-2 EN 60601-1-6 EN 60601-1-11 EN 62366 EN 62304 EN 62353 IEC TR 60601-4-2 EN ISO 14971 EN ISO 15223-1	IEC 60601-1 IEC 60601-1-2 EN 60601-1-6 EN 60601-1-11 EN 62366	Equivalent
Sterilization	Not provided sterile	Not provided sterile	Equivalent

Biocompatibility testing

The components of the Limfa® Therapy system do not contact patient skin, so such testing was not required. They do contact user intact skin but are identified by the FDA as having low risk when in contact with intact skin. The cover of the Emitter is silicone. The cover of the Total Body Mat is phthalate-free PVC.

Software testing

According to the FDA's Guidance for Industry and FDA Staff, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, the software for this device is considered to have a "moderate" level of concern.

Performance Testing

The electromagnetic compatibility and safety testing and other performance testing were conducted in accordance to the following standards:

- EN 60601-1: 2006 / A11: 2011 / A1: 2013 Medical electrical equipment. Part 1: General requirements relating to basic safety and essential performance
- EN 60601-1-2: 2015/A1: 2021; IEC 60601-1-2: 2014/A1: 2020 – Medical electrical equipment – Part 1: General requirements for safety and general requirements – Collateral standard: electromagnetic

compatibility - Requirements and tests
- EN 62304: 2006 - Software for medical devices - Processes related to the software life cycle
- EN 62366: 2008 - Medical devices - Application of the engineering of the utilization characteristics to medical devices
- EN 62353: 2015 - Electro-medical equipment - Periodic checks and tests to be carried out after repairs to electro- medical equipment
- EN ISO 14971: 2019—Medical devices. Application of risk management to medical devices
- EN SIO 15223-1: 2021 – Symbols to be used in medical device labels, labeling, and information to be provided. Part 1: General requirements
- IEC TR 60601-4-2: Medical electrical equipment- Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

In all instances the Limfa® Therapy System functioned as intended and the results observed were as expected.

Animal Testing

No animal testing of the subject device was necessary. The performance tests are sufficient.

Clinical Studies

No clinical testing of the subject device was necessary. The performance tests are sufficient.

Conclusion

The information submitted in this premarket notification confirms that the Limfa® Therapy System raises no new questions of safety and effectiveness and that it is substantially equivalent to the predicate devices.