March 5, 2021

Eva Medtec, Inc
Irene Waldridge
Chief Technology Officer/Director of the Board
6300 W. Old Shakopee Road, Suite 140
Bloomington, Minnesota 55438

Re: K202693
Trade/Device Name: NeoWave Pain Relief and Recovery System, Model# T16-2020
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP
Dated: October 16, 2020
Received: October 19, 2020

Dear Irene Waldridge:

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,

Jitendra Virani
Acting 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202693

Device Name
NeoWave Pain Relief and Recovery System, Model# T16-2020

Indications for Use *(Describe)*

The NeoWave Pain Relief and Recovery System is indicated for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated areas in people who are in good health. The NeoWave Pain Relief and Recovery System simulates the kneading and stroking of tissues by using inflatable air channels.

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.

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SECTION 5: 510(K) SUMMARY

1. **Submitter:**

   Eva Medtec, Inc.
   6300 W. Old Shakopee Road, Suite 140
   Bloomington, MN 55438
   Contact Person: Irene Waldridge, Chief Technology Officer and Chairman of the Board
   Date Prepared: October 16, 2020

2. **Device:**

   Name of Device: NeoWave Pain Relief and Recovery System, Model# T16-2020
   Common or Usual Name: Powered Inflatable Tube Massager
   Classification Name: Massager, Powered Inflatable Tube (21 CFR 890.5650)
   Regulatory Class: II
   Product Code: IRP

3. **Predicate Device:**

   Relaxor Perfect Touch Air Massaging System
   Applicant: Salton, Inc. (Washington, DC)
   510(k) Number: K030437

4. **Device Description:**

   The NeoWave Pain Relief and Recovery System Model # T16-2020 is a reusable, non-sterile therapy device intended to provide a gentle, rhythmic, soothing sensation using timed, pre-programed air pressure to inflate and deflate air channels within the therapy attachments. Each air channel inflates then deflates one at a time, to simulate the press and release action of the human hand by manipulating the soft tissues of the body relieving pain and increasing circulation.

   This device is a gradient, sequential, pneumatic compression device intended for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated areas in people who are in good health. The NeoWave Pain Relief and Recovery System simulates the kneading and stroking of tissues by using inflatable air channels.

   The NeoWave Pain Relief and Recovery System consists of an air compressor, valve module(s) and a therapy attachment working together as one unit. The therapy attachments contain one or two valve modules that connect to the Controller Unit via a

series of receptacles, tubing, and cabling. The system uses an external power supply of 12V DC.

The Therapy Attachments/Cushions consist of inflatable welded pads with 8 or 16 air channels. The massage direction is distal to proximal (toward the heart). The sequential inflation cycle inflates then deflates one air channel at a time, for 3, 4 or 5 seconds allowing the user/patient to adjust the pressure. The therapy attachment/cushion works under the action of the valve module sensor and microprocessor.

5. Indications for Use:

The NeoWave Pain Relief and Recovery System is indicated for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated areas in people who are in good health. The NeoWave Pain Relief and Recovery System simulates the kneading and stroking of tissues by using inflatable air channels.

The Indications for Use statement for the NeoWave Pain Relief and Recovery System is identical to the predicate device.

6. Summary of Comparison of Technology Characteristics:

Powered inflatable tube massager is the technological principle for both the subject and the predicate devices. It is based on the use of inflating/deflating tubes/channels within a garment or attachment with air. Both devices simulate the kneading and stroking of tissues with the hands by use of an inflation pressure cuff.

The technology characteristics of the NeoWave system, e.g., overall device design, materials, mechanism of action, mode of operation, performance characteristics, intended use and type of use (reusable) is substantially equivalent to the predicate device; Relaxor Perfect Touch Air Massaging System.

Summary Table of Device Comparison

Table 12	Device Comparison		
Parameter	**Subject Device**	**Predicate Device**	**Comparison**
Manufacturer	**EVA MEDTEC, INC.**	**SALTON, INC.**	N/A
510(K) Number	K202693	K030437	N/A
Model Name	NeoWave System T16-2020	Relaxor Perfect Touch Air Massaging System	N/A
Classification	Class II Device, IRP (21 CFR890.5650)		Same
Indications for Use	The NeoWave Pain and Recovery System is indicated for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated areas in people who are in good health. The NeoWave simulates kneading and stroking of tissues by using inflatable air channels.	The Perfect Touch Air Massaging System is indicated for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated areas in people who are in good health. The Perfect Touch simulates kneading and stroking of tissues by using an inflatable garment.	Same
OTC or Rx	OTC		Same
Environment Of Use:	Home or clinical environment	Home environment	Same
Standards	IEC 60601-1: 2005 IEC 60601-1-2: 2014 IEC 60601-1-11: 2015 IEC 60601-1-6:2010 ISO 10993-10: 2010 ISO 10993-5: 2009	Not available	Same, Meets consensus standards for ES, EMC & Biocompatibility
Principle of Operation	Sequential pneumatic compression		Same
Power Source	120V, 60Hz		Same
Therapy Time	Has 15- or 30-minute sessions, up to 30 minutes in one session, can be used up to twice daily for 60 minutes.	Has 15-minute sessions, up to 30 minutes in one session, can be used up to twice daily for 60 minutes.	Same
Number of Chambers	16 Chambers – Neck/Back Cushion 8 Chambers – Lumbar Cushion	12 chambers	Minor difference see note in Section 12.3.5

Section 5: 510(k) Summary

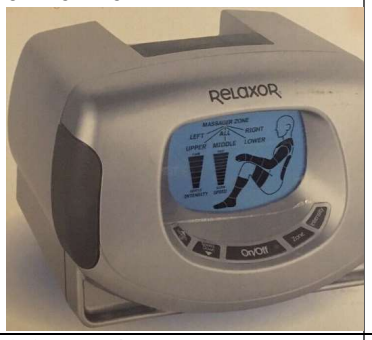
Table 12	**Device Comparison**		
Parameter	**Subject Device**	**Predicate Device**	**Comparison**
Compression Applicator Cushion/ Garments Sleeve Material	Compression applicator (inflatable air channels inside the therapy attachments): Nylon with a Polyurethane laminate Outer therapy attachment cover material: 72% Polyester, 6% spandex microfleece, 28% PU film	Nylon with a polyurethane laminate	Similar, see note in Section 12.3.6
Patient Contact	Non-conductive attachments		Same
Sterility of the Device	Non-Sterile		Same
Power Consumption	30W	26W	Similar, see note in Section 12.3.7
Cycle Time	3 sec, 4 sec or 5 sec per chamber Range of 24 sec to 1 min 20 sec	Range of 15 sec to 1 min 5 sec	Similar, see note in Section 12.3.3
Size and Photo	8.5” x 4.25” x 7.25” 	9” x 6” x 6” 	Similar, see note in Section 12.3.1
Weight	3 pounds	3.2 pounds	Similar, difference is immaterial
Housing Materials and Construction	Molded ABS/PC enclosure	Molded ABS enclosure	Similar, see note in Section 12.3.1
Reusable Life	Multi Use		Same
Min & Max Inflation Pressure	Intermittent 113 to 149 mm Hg 3 Pressure Levels Mild – 113-144 mm Hg Medium – 127-147 mm Hg Intense – 134-149 mm Hg	Intermittent 80 to 200 mm Hg 6 intensity settings 1 – 80 mm Hg 2 – 104 mmHg 3 – 128 mm Hg 4 – 152 mm Hg 5 – 176 mmHg 6 – 200 mmHg	Similar, Subject device pressures are within the range of the predicate, see note in Section 12.3.4
Modes (Inflation sequences, pre-programmed)	1 Mode: inflates and deflates chambers from bottom up (distal to proximal chambers). One at a time.		Same

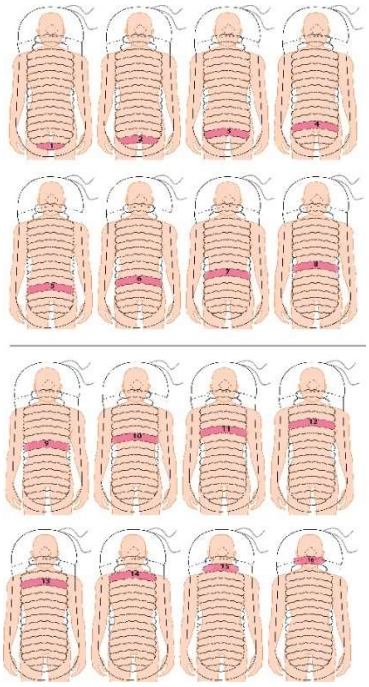
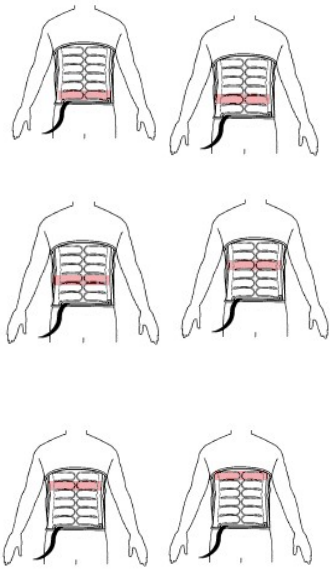
Table 12	**Device Comparison**		
Parameter	**Subject Device**	**Predicate Device**	**Comparison**
Mode Visual Description of inflation sequence	 Inflation sequence starts from the bottom of the cushion and ends at the neck area		Same, except NeoWave has more air chambers

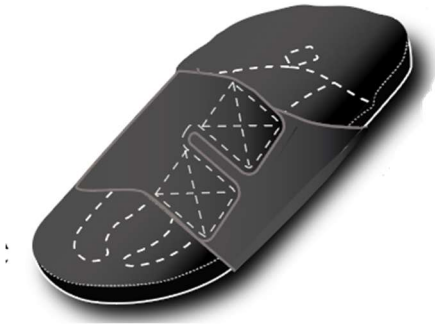
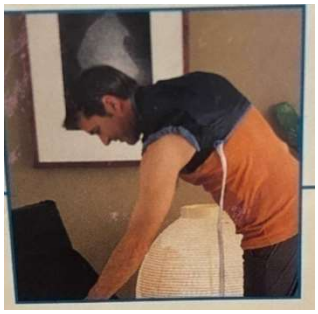
Table 12	**Device Comparison**		
Parameter	**Subject Device**	**Predicate Device**	**Comparison**
Neck/Back Cushion Picture/ Photo	Neck/Back (consisting of lower and mid back and neck)  	Back (consisting of lower and mid Back)   Neck (consisting of upper back and neck)	Similar, see note in Section 12.3.2
Lumbar Cushion Picture	Back (consisting of lower and mid back) 	Back (consisting of lower and mid back)  	Same

Table 12	Device Comparison		
Parameter	**Subject Device**	**Predicate Device**	**Comparison**
Safety Features	Button on the display allows user to stop or pause therapy session at any time.		Same
SW/Firmware/ Microprocessor Control	Microprocessor		Same
Technology	Compressor and valve system which sequentially inflate air channels of the appliance/therapy attachment		Same

The NeoWave system has been compared with the Relaxor Perfect Touch Air Massaging system (K030437). The subject device has the same intended use and principles of operation, similar technological characteristics as that of the predicate devices. Although there are a few differences in specifications, a comparison analysis was completed to demonstrate that the differences would not adversely impact the safety and effectiveness of the subject device.

7. Performance Data

The following performance data are provided in support of the substantial equivalence determination.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the NeoWave Pain Relief and Recovery System consisting of the Controller Unit and therapy attachments. The system complies with IEC 60601-1 Ed 3.1: 2005, IEC 60601-1-11: 2015 standards for safety and the IEC 60601-2: 2014 standard for EMC.

Biocompatibility testing

The Biocompatibility evaluation for the NeoWave Pain Relief and Recovery System was conducted in accordance with ISO 10993-1:2018 Biological Evaluation of Medical Devices. The system complies with ISO 10993-5:2009 & ISO 10993-10:2010.

Shipping/Packaging Testing

Testing was performed on the finished NeoWave Pain Relief and Recovery System and its finished packaging. The packaging consists of an interior box with foam where the Controller Unit is positioned and then placed inside a shipping box along with a therapy attachment as a system. The system was tested and complies with ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices." The software for this device is considered as a "moderate" level of concern since a failure or latent design flaw could indirectly result in a minor injury to the patient.

Mechanical Bench Testing

Performance verification testing was conducted based upon the systems Device Design Requirements. The system meets all device design criteria.

- Controller Unit Assembly Performance
- Valve Module Assembly Performance
- Cable/Tubing Assembly Performance
- Neck/Back Cushion Assembly Performance
- Lumbar Cushion Assembly Performance
- Life Cycle Performance

Usability Testing

A summative study was conducted by Eva Medtec and concluded the system met all pre-defined usability requirements and all usability risks have been adequately mitigated.

The System's Usability Engineering File was evaluated and is compliant with IEC 60601-1-6: 2010 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard.

8. Conclusion

Based upon safety and performance testing, compliance with voluntary standards, and comparison to the predicate devices, the manufacturer believes that the NeoWave Pain Relief and Recovery System is substantially equivalent to the predicate device and does not raise any new questions of safety or effectiveness.

The non-clinical data supports the safety of the device and the hardware/software verification and validation demonstrate that the NeoWave device performs as intended under the specified use conditions.