September 2, 2021

Diode Art Engineering doing business as Air Relax
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K212491
Trade/Device Name: Air Relax Pro Model AR-4.0
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP
Dated: August 7, 2021
Received: August 9, 2021

Dear Prithul Bom:

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212491

Device Name

Air Relax Pro Model AR-4.0

Indications for Use *(Describe)*

The Air Relax Pro Model AR-4.0 is intended for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Air Relax Pro Model AR-4.0 simulates kneading and stroking of tissues by using an inflatable garment.

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

Prescription Use (Part 21 CFR 801 Subpart D) [X] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
K212491

Date Prepared:	July 23, 2021
Applicant	Diode Art Engineering doing business as Air Relax 9535 Brasher St Pico Rivera, CA 90660 Tel – 1.323.285.4231
Official Contact:	Beomjoon Lee, General Manager
Proprietary or Trade Name:	Air Relax Pro Model AR-4.0
Common/Usual Name:	Powered Inflatable Tube Massager
Classification Name:	IRP - Massager Powered Inflatable Tube (CFR 890.5650)
Predicate Devices:	K211460 – Air Relax Model AR-3.0

Device Description:
This submission is for the Diode Art Engineering Air Relax Pro Model AR-4.0. The Air Relax Pro Model AR-4.0 is a powered inflatable tube massager. It is intended to temporarily relieve minor muscle aches and pains, and to temporarily increase circulation to the treated areas. It simulates manual kneading and stroking of tissues by use of an inflatable pressure cuff. The device is to be used by people who are in good health.

The device is a Class II, type BF applied part that receives power a separately approved external IEC 60601-1 compliant power supply or optional battery pack.

The Air Relax Pro Model AR-4.0 consists of an air compressor unit with a control system, an inflatable "garment" (arms, legs and hips), plastic air tubing with a proprietary connector for connecting the device to the garment. A description of each of these components is provided below. The hip garment is also referred to as "shorts".

The user interface is a front panel display and buttons.

The Air Relax Pro Model AR-4.0 contains an air compressor with a system control that that allows the user to adjust the amount of air coming from the air compressor and going to the individual segments of the inflatable garment.

There is no electrical contact with the user and the device does not transfer or detect energy to or from the user.

The user interface of the Air Relax Pro Model AR-4.0 provides for starting and stopping the massage treatment, allows for adjusting time and intensity (pressure) of the treatment. The device also provide a proprietary keyed connector to the tubing

which connects to the garment. The tubing connector at the garment is also proprietary. The proprietary connectors ensure that neither the device, tubing nor garment can be misconnected to any other device or garment.

Pressure selection is performed by pressing pressure button multiple times. Pressure level is selectable between 40 and 170 mmHg

There are four modes (Progressive, Sequential, Drain and Overlay) that determine the inflation sequence of the cells within the garments..

Intended Use / Indications for Use:
The Air Relax Pro Model AR-4.0 is intended for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Air Relax Pro simulates kneading and stroking of tissues by using an inflatable garment.

Patient Population:
Adults

Environments of Use:

Clinics, hospital, athlete training, and home environments

Table of the Similarities and Differences of Subject vs. Predicate Device

Model Name 510(k) Number	Subject Device Air Relax Pro Model AR-4.0 K212491	Predicate Device Air Relax Plus Model AR-3.0 K211460	Comment
Classification	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21 CFR890.5650)	Identical
Indications for use	The Air Relax Pro Model AR-4.0 is intended for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Air Relax Pro Model AR-4.0 simulates kneading and stroking of tissues by using an inflatable garment	The Air Relax Plus Model AR-3.0 is 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 Air Relax Plus Model AR-3.0 simulates kneading and stroking of tissues by using an inflatable garment	Identical
OTC or Prescription	OTC	OTC	Identical
Environment of Use	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	Identical
Compliance with standards	ES 60601-1, IEC 60601-1-2, IEC 60601-1-11	ES 60601-1, IEC 60601-1-2, IEC 60601-1-11	Identical
Mode of Operation	Sequential/Peristaltic	Sequential/Peristaltic	Identical
Power	100~240V, 50/60Hz	100~240V, 50/60Hz	Identical
Device Pressure range	40 - 170 mmHg	60 - 170 mmHg	Similar to predicate except low pressure, it does not affect safety and effectiveness.
Garments material	Nylon with a Polyurethane Laminate	Nylon with a Polyurethane Laminate	Identical
Leg Attachment	Yes Size “2” : 34 X 15.35 Size “3” : 38.2 X 15.35 Size “4” : 42 X 15.35	Yes Size “2” : 34 X 15.35 Size “3” : 38.2 X 15.35 Size “4” : 42 X 15.35	Identical in size and materials. Number of Inflatable garment segments differs.

510(k) Summary

Model Name 510(k) Number	Subject Device Air Relax Pro Model AR-4.0 K212491	Predicate Device Air Relax Plus Model AR-3.0 K211460	Comment
Arm Attachment	Yes Size "1" : 34 X 15.35 Size "2" : 39.3 X 15.35	Yes Size "1" : 34 X 15.35 Size "2" : 39.3 X 15.35	Identical in size and materials. Number of Inflatable garment segments differs.
Shorts Attachment	Yes Size "1" : 20.8 X 32.5 Size "2" : 24.6 X 32.5	Yes Size "1" : 20.8 X 32.5 Size "2" : 24.6 X 32.5	Identical in size and materials. Number of Inflatable garment segments differs.
Number of Inflatable garment segments	6	4	No impact on safety and effectiveness
Weight	2.2 kg (4.85 pounds)	1.67kg (3.7 pounds)	Weight is different but it does not affect safety and effectiveness.
Dimensions (W x H x D)	7.7" x 7.1" x 10.4"	9.5" x 4.7" x 7.5"	Size is different but it does not affect safety and effectiveness.
Housing Materials and Constructions	Molded ABS enclosure	Molded ABS enclosure	Identical
Patient contact	Non-conductive garments	Non-conductive garments	Identical
Safety Features	Button at control unit allows user to stop or pause therapy session at any time.	Button at control unit allows user to stop or pause therapy session at any time.	Identical
Modes	4 Modes : "PROG" mode inflates and deflates chambers from bottom up, one at a time "SEQT" mode also inflates chambers from bottom up, but maintains pressure in lower chambers as works its way to top.	4 Modes : "P" mode inflates and deflates chambers from bottom up, one at a time "S" mode also inflates chambers from bottom up, but maintains pressure in lower chambers as works its way to top.	Similar to predicate. Differences do not affect safety and effectiveness.

Model Name 510(k) Number	Subject Device Air Relax Pro Model AR-4.0 K212491	Predicate Device Air Relax Plus Model AR-3.0 K211460	Comment
	"OVLAY" mode is inflates all chambers and maintained pressure at same time and release pressure all chambers. "DRAIN" mode is mixed mode of SEQT and PROG	"F" mode is inflates all chambers and maintained pressure at same time and release pressure all chambers. At "Target" mode, user can select specific chamber to inflates	
Treatment Duration	5-95 minutes	15 or 30 minutes	Extended duration for subject device but predicate time can be re-enabled any number of times so no significant difference

Substantial Equivalence Discussion

In the above detailed table we have compared the Air Relax Pro Model AR-4.0 to the predicate for equivalence of:

Indications –

The Air Relax Pro Model AR-4.0 is intended for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Air Relax Pro Model AR-4.0 simulates kneading and stroking of tissues by using an inflatable garment.
These indications are identical to the predicate.

Prescriptive – The Air Relax Pro Model AR-4.0 is OTC as is the predicate

Design, Technology and Principle of Operation – The Air Relax Pro Model AR-4.0 has equivalent design and features when compared to the predicate and have identical technology to the predicate

Performance and Specifications – The Air Relax Pro Model AR-4.0 has equivalent specifications of performance when compared to the predicate.

Compliance with standards – The Air Relax Pro Model AR-4.0 declares compliance with IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-2 which is identical to the predicate.

Materials –
The patient contacting materials of the Air Relax Pro Model AR-4.0 are the inflatable garments which are identical to the predicate device 510(K) K211460

Patient Population –
The Air Relax Pro Model AR-4.0and predicate are indicated for adults

Environment of Use –
The Air Relax Pro Model AR-4.0 and predicates are for use in clinics, hospital, athlete training, and home environments.

Differences –
There are no differences between the proposed device and the predicate device that raise any new safety and efficacy concerns.

Performance Testing

Bench:

The device has been tested to insure that it all requirements have been met, this includes:

- Testing of all controls
- Testing of all indicators
- Testing of performance

The device has also been tested to the requirements of the following standards:

- AAMI / ANSI ES60601-1:2005 + A1: 2012 Medical electrical equipment - part 1: general requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 Collateral standard: Electromagnetic Disturbances - Requirements and Tests
- IEC 60601-1-11: 2015, Collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Animal:
No animal testing was performed

Clinical:
No clinical testing was performed

Differences –
There are no differences between the proposed device and the predicate device that raise any new safety and efficacy concerns.

Substantial Equivalence Rationale

The Air Relax Pro Model AR-4.0 is viewed as substantially equivalent to the predicate device because:

Indications – are identical to the predicate

Prescriptive – The Air Relax Pro Model AR-4.0 and predicate are OTC.

Design, Technology and Principle of Operation – The Air Relax Pro Model AR-4.0 has equivalent design and features when compared to the predicate and have the identical technology to the predicate.

Performance and Specifications – The Air Relax Pro Model AR-4.0 has equivalent specifications of performance when compared to the predicate.

Compliance with standards – The Air Relax Pro Model AR-4.0 declares compliance with IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-2 which is identical to the predicate

Materials – The patient contacting materials of the Air Air Relax Pro Model AR-4.0 are are identical to the predicate.

Environment of Use – Clinics, hospital, athlete training, and home environments, identical to the predicate.

Features - The Air Relax Pro Model AR-4.0 has equivalent features when compared to the predicate.

Conclusion
The Air Relax Pro Model AR-4.0 is substantially equivalent to the predicate in: indications for use, patient population, environment of use, technology characteristics, materials, specifications / performance and compliance with international standards. Minor differences as detailed in the substantial equivalence table above do not raise questions of safety and effectiveness.