October 21, 2021

Pollogen, Ltd
% Amaya De Levie
RA Director
Benjamin L. England and Associates
810 Landmark Dr, Suite 126
Glen Burnie, Maryland 21061

Re: K200545
Trade/Device Name: Legend Pro DMA
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: September 14, 2021
Received: September 22, 2021

Dear Amaya De Levie:

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,

Vivek Pinto, PhD
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)*
K200545

Device Name
Legend Pro DMA

Indications for Use *(Describe)*
Legend Pro DMA is intended for muscle conditioning to stimulate healthy muscles.

Legend Pro DMA is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.

Legend Pro DMA is intended to be operated by a trained professional who is present to monitor treatment

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

K200545

Applicant Name:	Udi Russo Pollogen Ltd. 6 Kaufman Street Tel Aviv, Tel-Aviv, ISRAEL 6801298 Phone: +972 3 5104110 Fax: +972 3 5104112
Contact Person:	Amaya De Levie Lumenis Ltd. 6 Hakidma Street PO Box 240, Yokneam Industrial Park Yokneam 2069204 Israel Phone: +972-549599073 E-mail: Amaya.delevie@gmail.com
Date Prepared:	October 20, 2021
Trade Name:	Legend Pro DMA
Classification Name:	Stimulator, Muscle, Powered, For Muscle Conditioning
Product Code:	NGX
Device Class:	Class II
Regulation Number:	21 CFR 890.5850
Panel:	Physical Medicine
Predicate Device:	Body System (K182440)
Reference Device	AK Body Toning Device (K152420)

Intended Use/ Indications for Use:

Legend Pro DMA is intended for muscle conditioning to stimulate healthy muscles.

Legend Pro DMA is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.

Legend Pro DMA is intended to be operated by a trained professional who is present to monitor treatment.

Device Description:

The Legend Pro DMA generates a sequence of electrical pulses which are delivered to the skin overlaying the muscles intended to be stimulated. The Legend Pro DMA consists of a floor-mounted, rolling System Console that generates voltage output delivered though metal electrodes in the three different DMA Applicators. The System Console generates electrical pulses, and delivers modulated low frequency rectangular biphasic waveforms via electrodes incorporated in different Applicators connected to the System Console:

- LP DMA Applicator No. 1 for large Areas (includes 6 stainless-steel equidistant electrodes)
- LP DMA Applicator No. 2 for Medium areas (includes 3 stainless-steel equidistant electrodes)
- LP DMA Applicator No. 3 for Small Areas (includes 3 stainless-steel equidistant electrodes)

The Legend Pro DMA is controlled by a proprietary embedded SW. The system SW provides the treatment parameters. The hardware (HW) then implements the actual pulse generation according to the parameters provided by the software. Via the GUI in the System Console, the physician selects the Applicator according to the size of the area being treated and the treatment parameters (Frequency, % Height/Amplitude, pulse width and Treatment Duration). During the treatment session, the operator moves the Applicator across the skin that is lubricated with glycerine.

Summary of Technological Characteristics

Parameter	Legend Pro DMA	Principal Predicate Device	Reference Device	Same/ Similar/Different
510(k) Number	K200545	K182440	K152420	
Device Name and Model	Legend Pro DMA	Body System	AK Body Toning Device	N/A
Manufacturer	Pollogen	A-1 Engineering	AK Beauty Enterprises, LLC	
Product Code	NGX	NGX	NGX	Same
Type of Use	Prescription Use (Part 21 CFR 801 Subpart D)	Prescription Use (Part 21 CFR 801 Subpart D)	Over-The-Counter Use (21 CFR 801 Subpart C)	Same
Intended Use	Legend Pro DMA **is intended for muscle conditioning to stimulate healthy muscles.** Legend Pro DMA **is not intended to be used in conjunction with therapy or**	The Body System **is intended for muscle conditioning to stimulate healthy muscles.** The Body System **is not intended to be used i**n conjunction with	The AK Body Toning Device is intended for use by healthy persons to apply transcutaneous electrical muscle stimulation (EMS) through skin-contact electrodes in order to improve or facilitate muscle performance.	Same Intended use as the Predicate. Similar to the Reference

Parameter	Legend Pro DMA	Principal Predicate Device	Reference Device	Same/ Similar/Different
510(k) Number	K200545	K182440	K152420	
Device Name and Model	Legend Pro DMA	Body System	AK Body Toning Device	N/A
	treatment of **medical diseases or medical conditions**. Legend Pro DMA **is intended to be operated by a trained professional who is present to monitor treatment.**	**therapy or treatment of medical diseases or medical conditions of any kind.** The Body System **is intended to be operated by a trained professional who is present to monitor treatment.**		
Mode of Operation	Application of transcutaneous electrical muscle stimulation (EMS) through skin-contact electrodes	Application of transcutaneous electrical muscle stimulation (EMS) through skin-contact electrodes	Application of transcutaneous electrical muscle stimulation (EMS) through skin-contact electrodes	Same mode of operation as the Predicate and Reference
Mode of application	Metal (Stainless steel) electrodes in the System Applicator emit electric energy to the skin while the system applicator is rolled across the treatment area	Fixed self-adhesive, gelled pad applicators attached to the skin for muscle conditioning.	Metal electrodes in the device emit electric energy to the skin while the device is rolled across the treatment area	Different from the predicate (moving electrodes vs. fixed electrodes) but similar to the Reference device. See Section 12.4.
Body Application Areas	Body	Body	Not publicly available	
Power Source(s)	110-240 V 50-60 Hz	110-240 vac (AC wall plug-In) 50 - 60 Hz	Battery 3 x 1.5 V AAA batteries	Same as the Predicate. Different from the Reference device
Method of Line Current Isolation	Medical Power Supply, Transformer in output stage	Power Supply isolation	N/A - Internal Power Type BF	Similar to the Predicate
Patient Leakage Current				
- **Normal Condition (µA)**	1.5 µA	.05 µA	N/A (battery operated device)	Similar to the Predicate
- **Single Fault Condition (µA)**	40 µA	5 µA	N/A (battery operated device)	Similar to the Predicate and below 500 µA value in guidance.
Number of Output Modes	1	5	1	Different. Modes are comparable. No issues of safety or effectiveness
Number of Output Channels:	1	16	1	Different. Each session will use one of three Applicators. No difference in safety or effectiveness.

Parameter	Legend Pro DMA	Principal Predicate Device	Reference Device	Same/ Similar/Different
510(k) Number	K200545	K182440	K152420	
Device Name and Model	Legend Pro DMA	Body System	AK Body Toning Device	N/A
				Applicator is moved to cover entire treatment area.
Synchronous or Alternating?	N/A Single output channel.	Synchronous	N/A Single channel.	Different. Not required for one output channel
Method of Channel Isolation	N/A Single output channel.	Power Supply isolation	N/A Single channel.	Different. Single channel does not require channel isolation.
Regulated Current or Regulated Voltage?	Voltage	Current and Voltage	Voltage	Similar to the Predicate. Different form the Reference device
Software/Firmware/Microprocessor Control?	Yes	No	No	Different. The software is validated. The output from each is comparable. Does not directly affect safety and effectiveness.
Automatic Overload Trip?	No	Yes	No	Same as the Reference. Different from the predicate device
Automatic No-Load Trip?	No	Yes	No	Same as the Reference. Different from the predicate device
Automatic Shut Off?	No	Not publicly available	Yes	Different.
Patient Override Control?	Yes	Not publicly available	Yes	Similar to the Reference device. Patient-Controlled Manual Switch used as a patient control in the case of discomfort that stop power transmission immediately after the patient presses the button
Indicator Display:				
- **On/Off Status**	Yes	Yes	Yes	Similar to Predicate and Reference
- **Low Battery**	N/A	N/A	No	N/A
- **Voltage/Current Level**	Voltage	Yes	Proportional Voltage level indicator	Similar to the Predicate and Reference Controlled/displayed via GUI
- **Timer Range (minutes)**	1-99 min	None	5 min	Similar to Predicate and Reference

Parameter	Legend Pro DMA	Principal Predicate Device	Reference Device	Same/ Similar/Different
510(k) Number	K200545	K182440	K152420	
Device Name and Model	Legend Pro DMA	Body System	AK Body Toning Device	N/A
Compliance with Voluntary Standards?	Yes IEC60601-1 IEC60601-1-2 IEC60601-2-10 IEC62304 ISO 10993	Yes Electrical Safety: Comply with IEC 60601-1 and IEC 60601-2-10 EMC: Comply with IEC 60601-1-2 Biocompatibility: ISO10993-5 and ISO10993-10	Yes IEC 60601-1 IEC 60601-1-2 UL 60601-1 (2003) CSA C22.2 No. 601.1 IEC 60601-2-10	Similar to Predicate and Reference.
Compliance with 21 CFR 898	Yes	Yes	N/A (electrodes are integral with the device, there are no separate leads)	Compliant with 60601-1
Weight (lbs., oz.)	~30 Kg; 66 lbs	Not publicly available	800 g	N/A
Dimensions (in.) [W x H x D]	45 x 110 x 45 cm 17.7 x 43.3 x 17.7 in	Not publicly available	3.12 x 3.51x 7.0 (IN)	N/A
Housing Materials and Construction	Metal, Plastics	Aluminium	ABS	N/A

OUTPUT SPECIFICATIONS

Parameter	Legend Pro DMA	Principal Predicate Device	Reference Device	Similar/Different
510(k) Number	K200545	K182440	K152420	
Device Name and Model	Legend Pro DMA™	Body System	AK Body Toning Device	N/A
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic	Monophasic	Similar to Predicate and different from Reference
Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular	Rectangular	Rectangular	Similar to Predicate and Reference
Maximum Output Voltage (volts) (+/- 10%)	60V@500Ω 3.95V_{RMS}@500Ω	58V@500 Ω V_{RMS} not publicly available but not higher than 10V_{RMS} to meet 60601-2-10	10.4V@500Ω V_{RMS} not publicly available but not higher than 10V_{RMS} to meet 60601-2-10	Similar to Predicate
	200V@2000Ω 12.3V_{RMS}@2000Ω	88V@2000Ω V_{RMS} not publicly available	35.6V@2000Ω V_{RMS} not publicly available	Different from predicate but not higher than 10V_{RMS} @500 Ω to meet 60601-2-10
	360V@10000Ω 17.6V_{RMS}@10000Ω	Not publicly available	88.0V@10000Ω V_{RMS} not publicly available	Predicate information not publicly available. Different from reference but not higher than 10V_{RMS} @500 Ω to meet 60601-2-10

Parameter	Legend Pro DMA	Principal Predicate Device	Reference Device	Similar/Different
510(k) Number	K200545	K182440	K152420	
Device Name and Model	Legend Pro DMA™	Body System	AK Body Toning Device	N/A
Maximum Output Current (mA@ Ω) (+/- 10%)	120mA@500Ω	108mA@500 Ω	22 mA@500Ω	Similar to the predicate
	100mA@2000Ω	Not publicly available	18 mA@2000Ω	Predicate information not publicly available
	36mA@10000Ω	Not publicly available	9mA@10000Ω	Predicate information not publicly available
Pulse Width (µsec)	20 to 400 µsec	500 to 2500 µsec	1000 µsec	Different from predicate but does not raise issues of safety or effectiveness
Phase duration	10 to 200 µsec	Not publicly available	Not publicly available	N/A
Frequency (Hz)	0.78, 1.56, 3.13, 6.25; 12.5 Hz	200 to 1200 Hz	75 Hz	Different from Predicate, similar to Reference
Net Charge (microcoulombs (µC) per pulse) (If zero, state method of achieving zero net charge.)	0 @ 500Ω biphasic waveform Zero net charge is achieved by using symmetrical biphasic waveforms	0 @ 500 Ω Zero net charge is achieved by using symmetrical biphasic waveforms	22.5 µC @500Ω	Similar to Predicate
Maximum charge per Phase, (µC)	24µC @ 500Ω @12.5Hz	45 µC @ 500 Ω @ 200 Hz	22.5 µC @500Ω	Similar to Predicate and Reference
Maximum Current Density, (mA/cm²)	1.1mA/cm^2 @ 500Ω	5 mA / cm^2	4.17 mA/cm^2 @500Ω	Similar to Predicate and Reference
Maximum Power Density (W/cm²),	0.0044 W/cm^2 @ 500Ω	0.012 W/cm^2	0.0089W/cm^2 @ 500Ω	Similar to Predicate and Reference
Burst Mode (i.e., pulse trains):	N/A no burst mode	Not publicly available	N/A, no burst mode	Similar to Reference

Substantial Equivalence

The Legend Pro DMA shares with its principal predicate, the Body System (K182440), exactly the same intended use:

Legend Pro DMA is substantially equivalent to another legally marketed device, the Body System (K182440). The subject device, Legend Pro DMA, has the same general intended use and similar indications, technological characteristics, and principles of operation as the previously cleared predicate, the Body System (K182440). The Legend Pro DMA, similarly, to the Body System, is an electrical Muscle Stimulator for prescription use with a biphasic rectangular waveform, is voltage regulated and uses similar underlying technology and performance envelope. In addition, the Legend Pro DMA, meets the same safety standards, including biocompatibility and electrical safety. Provided as a reference, the AK Body Toning Device (K152420) was also included in the comparison tables in order to support the mode of the energy application to the target, as it uses non-stationary electrodes, similar to the electrodes and applicators used in the Legend Pro DMA. Overall, these three systems have the same principle of operation, applying transcutaneous electrical muscle stimulation (EMS) through skin-contact electrodes, and they all share the same intended use.

Performance Data

The Legend Pro DMA has been tested to establish its safety and performance. The following design verification and validation processes were performed according to the FDA Guidance Document for Powered Muscle Stimulator 510(k)s Document issued on: June 9, 1999 and based on the Predicate device, the Body System, K182440:

- Risk analysis per ISO 14971
- Electrical, electromagnetic compatibility safety testing according to IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-10.
- Software verification and validation according to IEC 62304 and FDA Guidance “Principles of Software Validation Guidance for Industry and FDA Staff, January 2002”.
- Performance testing (e.g., energy measurements, including Output Waveforms).
- Reprocessing evaluation according to FDA’s guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling FDA Guidance (2015, Updated June 9, 2017)”.
- Biocompatibility evaluation according to ISO 10993-1 and FDA Guidance “Use of International Standard ISO 10993-1, “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing with a Risk Management Process, September 2020 and “Select Updates for Biocompatibility of Certain Devices in Contact with Intact Skin DRAFT”, October 2020

Clinical Testing

Not applicable.

Conclusion

Based on the intended use/Indications for use, design, materials, principle of operation, energy used and materials, the Legend Pro DMA is substantially equivalent to the legally marketed predicate device the Body System (K182440). The non-clinical performance data according to the FDA Guidance Document for Powered Muscle Stimulator 510(k)s Document issued on June 9, 1999, supports the substantial equivalence and includes an analysis of output waveforms.