August 25, 2023

Tonica Elektronik A/S
Dr. Kirstine Schou
Medical Writer
MagVenture A/S
Lucernemarken 15
Farum, DK-3520
Denmark

Re: K230014
Trade/Device Name: MagVenture Pain Therapy: MagPro R30, MagPro R30 with MagOption, MagPro X100, MagPro X100 with MagOption,
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: QPL
Dated: August 8, 2023
Received: August 8, 2023

Dear Dr. Schou:

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,

Amber T. Ballard -S

Amber Ballard, 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

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)*
K230014

Device Name
MagVenture Pain Therapy: MagPro R30, MagPro R30 with MagOption, MagPro X100, MagPro X100 with MagOption

Indications for Use *(Describe)*
To stimulate peripheral nerves for relief of chronic intractable, post traumatic and post-surgical pain for patients 18 years or older

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

510(k) Number K230014

DATE PREPARED
08/25/2023

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION
Proprietary Name/Trade Name: MagVenture Pain Therapy: MagPro R30, MagPro R30 with MagOption, MagPro X100, MagPro X100 with MagOption

Common name:	Electromagnetic stimulator, pain relief
Regulation Number:	21 CFR 882.5890
Regulation Name:	Transcutaneous electrical nerve stimulator for pain relief
Class:	Class II
Product Code:	QPL
Review Panel:	Physical Medicine

PREDICATE DEVICE IDENTIFICATION
The *MagVenture Pain Therapy* (K230014) is substantially equivalent to the following predicate:

510(k) Number	Predicate Device Name / Manufacturer	Predicate
K210021	Axon Therapy/ NeuraLace Medical, Inc.	√

DEVICE DESCRIPTION

The *MagVenture Pain Therapy* is a magnetic stimulator system that provides brief and focused magnetic pulses in order to non-invasively stimulate peripheral nerves and provide relief of chronic intractable, post-traumatic and post-surgical pain. The subject device is intended to be used in hospitals and clinics such as pain management clinics. The device consists of Magnetic Stimulator, Stimulation Coils, Liquid Cool Unit (optional), and a Trolley. All coils of the *MagVenture Pain Therapy* have a built-in thermo sensor to measure the temperature of the coil surfaces to prevent high temperature on the skin of the patient or operator. The temperature allowed by the system is maximum 43°C or between 44ºC and 48ºC for less than 10 minutes. The system will automatically disable if this maximum temperature is reached.

INDICATIONS FOR USE

The *MagVenture Pain Therapy* is intended to stimulate peripheral nerves for relief of chronic intractable, post-traumatic and post-surgical pain for patients 18 years or older.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Tonica Elektronik A/S believes that the *MagVenture Pain Therapy* is substantially equivalent to the predicate device based on the information summarized here:

The subject device has a similar design and dimensions and uses similar or identical materials as the predicate device cleared in K210021. The subject device has identical technological characteristics to the MagPro Family cleared in K091940. These technological characteristics have undergone testing ensuring that the device is as safe and effective as the predicate.
While both the subject and predicate device are magnetic stimulators, with similar technological characteristics, and stimulation patterns, the subject device includes circular magnetic coils in addition to the butterfly geometry of the predicate device. Also, the devices differ in the ranges of pulse frequencies, maximum repetition rates, and maximum output power. As discussed below, these technological differences do not raise different questions of safety and effectiveness.

Items	Subject device				Predicate device	Statement of equivalence
Trade Name	MagVenture Pain Therapy				Axon Therapy	Not applicable
Model Name	MagPro R30 (K091940)	MagPro R30 with MagOption (K091940)	MagPro X100 (K091940)	MagPro X100 with MagOption (K091940)		
510(k)	K230014				K210021	Not applicable
Manufacturer	Tonica Elektronik A/S				NeuraLace Medical, Inc.	Not applicable
Product codes/ Regulation Numbers	QPL (21 CFR 882.5890)				QPL (21 CFR 882.5890) IPF (21 CFR 890.5850)	Same
CLINICAL CHARACTERISTICS						
Indications for use	The MagVenture Pain Therapy is intended to stimulate peripheral nerves for relief of chronic intractable, post traumatic and post-surgical pain for patients 18 years or older.				The Axon Therapy is intended to stimulate peripheral nerves for relief of chronic intractable, post traumatic and post-surgical pain for patients 18 and older	Same
Anatomical sites	Any area, such as hand, arm,waist, buttock, thigh, calf, back and lower back etc.				Any area, such as hand, arm, chest, waist, buttock, thigh, calf, back and lower back etc.	Same
Treatment Facilities	Hospitals & Clinics				Hospitals & Clinics	Same
Treatment time	13 min per session (800 seconds)				13 min per session (800 seconds)	Same
TECHNOLOGICAL CHARACTERISTICS						
Pulse frequency	0.1-30 Hz (pps)	0.1-100 Hz (pps)			0-2 Hz (pps)	Substantially equivalent Refer to SE note 1
Pulse amplitude	0-100%				0-100%	Same

On-cycle duty period	2-800 seconds (0.5 Hz and up to 400 pulses)				2-800 seconds (0.5 Hz and up to 400 pulses)	Same
Off-cycle reset period	N/A				N/A	Same
Maximum repetition rate	30 pulses per second		100 pulses per second		2 pulses per second (pps)	Substantially equivalent Refer to SE note 1
Pulse Width	Biphasic (280-320 µsec)				Biphasic (290 µsec)	Substantially equivalent
Pulse mode	Standard				Standard	Same
Maximum output power	100% at 15 pps				100% at 2 pps	Substantially equivalent Refer to SE note 2
Waveform	Biphasic	Biphasic, Monophasic	Biphasic, Biphasic Burst, Monophasic	Biphasic, Halfsine, Biphasic Burst, Monophasic	Biphasic	Substantially equivalent All devices are capable of biphasic mode
Maximum coil temperature	43°C				41°C	Same. The system will automatically disable if this maximum temperature is reached
Peak Magnetic Field at coil surface (T)	1.15-2.6 T*				Not publicly available	Substantially equivalent Refer to SE note 3
Peak Magnetic Field Gradient dB/dt in coil center at 20mm distance from the coil surface	9-24 kT/s*				Not publicly available	Substantially equivalent Refer to SE note 3
Software/Firmware/ Microprocessor control	Yes				Yes	Same
Power Source	Power Supply via Isolation Transformer Power Supply: 120V~, 50/60 Hz.				Power Supply: 110V to 220V ac, 50/60 Hz.	Same
	Power consumption: Maximum 2700VA				Power consumption: 800VA Maximum, 115W idle	
User Interface	LED display				LED display	Same

Housing Material Construction	Stimulator: Aluminum, Aluzinc Coils: PVC, ABS, PA, POM	Stimulator: Al sheet EN AW 5754 Coil: ABS	Substantially equivalent
Applied Parts	Magnetic coils: MMC-140-II (K061645) MCF-140 (K061645) RT-120-II (K061645) MMC-90 (K061645) MCF-125 (K071821) Cool-B65 (K071821) Cool-125 (K071821)	Magnetic coil 60BF-NL	Substantially equivalent Refer to SE note 3
Applied Parts area	Butterfly coils: 150 mm Circular coils:110-126 mm Special coils: 160×80 mm	160 mm	Substantially equivalent Refer to SE note 3
Sterilization	Non-sterile when used	Non-sterile when used	Same
PERFORMANCE DATA			
Electrical Safety	Complies with IEC60601-1 v3.1	Complies	Same
Mechanical Safety	Complies with IEC60601-1 v3.1	Complies	Same
Chemical Safety	Complies with IEC60601-1 v3.1	Complies	Same
Thermal Safety	Complies with IEC60601-1 v3.1	Complies	Same
Radiation Safety	No radiation generated	Complies	Same
Biocompatibility	Complies with ISO 10993	Complies	Same
Standards	Company complies with EN ISO 13485	Complies	Same

*No technological differences from K091940, but the definition of Peak Magnetic Field at coil surface changed. Likewise, the definition of Peak Magnetic Field Gradient at coil surface changed to lower values at a distance of 20mm from coil surface.

Substantial Equivalence Note 1

Comparison of subject and predicate pulse frequencies and maximum repetition rates.

The pulse frequencies of 0.1-30 Hz and 0.1-100 Hz and maximum repetition rates of 30 pps and 100 pps of the subject device are wider and higher, respectively, than the predicate device with pulse frequencies of 0-2 Hz and a maximum repetition rate of 2 pps. These differences do not raise different questions of safety and effectiveness since:

- The subject device can stimulate at 0.5 Hz the same as the predicate device.
- In the instructions for use, it is specified that the treatment parameter is 0.5 Hz.

- The maximum repetition rates of 30 and 100 Hz are both within the range of physiological action potentials (from 0.05 to 500 Hz) of the human nervous system and thus pose no new risk to the patients.

- The subject device is substantially equivalent to the predicate device for the following treatment protocol as outlined in the instructions for use. Treatment parameters (e.g., repetition rate, pulses per train, number of trains, number of pulses, inter train interval, treatment time) that are not included in the treatment protocol have not been evaluated for effectiveness in the relief of chronic intractable, post traumatic and post-surgical pain for patients 18 years or older.

  TREATMENT PROTOCOL

  Three to four treatments over two months and maintenance therapy every 6 to 8 weeks is recommended.

Treatment level:	Individually estimated (% of maximum output power)
Repetition rate:	0.5 pps
Pulses per train:	10
Number of trains:	40
Number of pulses:	400
Inter train interval:	2 s
Treatment time:	13 min

In conclusion, higher ranges of pulse frequencies and higher maximum repetition rates do not raise any new or different questions of safety and effectiveness.

Substantial Equivalence Note 2
Comparison of subject and predicate maximum output power.

The maximum output power of the subject device is 100% in the range of 0.1 to 15 pps while the predicate device is 100% in the range of 0.5 to 2 pps. Consequently, at 2 pps the subject device and the predicate device are both able to obtain a maximum output of 100% signifying they are equally effective.

In conclusion, since both devices perform 100% at 2 pps there are no new issues of safety and effectiveness. The difference in maximum output power does not raise new or different questions of safety and effectiveness.

Substantial Equivalence Note 3
Comparison of Subject and Predicate Magnetic Coils

The subject device has both circular and butterfly coils while the predicate only has a butterfly coil. However, all the coils are basically constructed the same way: A cobber winding element encapsulated in a plastic housing.
The size of the magnetic field depends on the diameter and number of windings. The number of windings only varies slightly and the diameters of the subject device coils are close to the predicate coil.

Except for minor differences in geometry, the butterfly coils of the predicate and subject devices are similar. In comparison to the butterfly geometry, the circular coils have just one coil element. This gives a better usability with no rotation limitation. *All coils achieve the same intended use.* The differences in the electric field and spatial characteristics (maximum magnetic fields at the coil surface (T) and the magnetic gradients (dB/dt)) of the circular and butterfly geometries are negligible and have no documented impact on effectiveness or safety of the intended use.

It is concluded that the differences in coil geometry do not raise new or different questions of safety and effectiveness.

SUMMARY OF NON-CLINICAL TESTING

The subject device is identical to the MagPro Family device (K094019) in all features (e.g., design, dimensions, materials, biocompatibility), except for the indications for use. Therefore, no new bench testing is needed.

DISCUSSION

The subject device has the same intended use, indications for use, and similar technological characteristics, and principles of operation as the predicate device. Also, the target population, the dosage, the treatment procedure, and all specific protocol parameters (intensity, repetition rate, number of pulses) are identical for the subject and the predicate device.

The subject device has a broader range of pulse frequencies and higher maximum repetition rates compared to the predicate device. Still, both devices are able to run the stimulation protocol of 400 pulses at 0.5 Hz. Furthermore, the maximum repetition rates of the predicate device are all within the range of physiological action potentials of the human nervous system and thus pose no new risk to the patients. The maximum output power of the subject device is higher than the predicate devices. Nevertheless, both devices perform 100% at 2 pps signifying they are equally effective. The subject device is substantially equivalent to the predicate device for the treatment protocol as described above. Treatment parameters (e.g., repetition rate, pulses per train, number of trains, number of pulses, inter train interval, treatment time) that are not included in the treatment protocol above have not been evaluated for effectiveness in the relief of chronic intractable, post traumatic and post-surgical pain for patients 18 years or older.

Finally, the subject device has both circular and butterfly coils while the predicate only has a butterfly coil. However, all the coils are basically constructed the same way: a cobber winding element encapsulated in a plastic housing. Except for minor differences in geometry, the butterfly coils of the predicate and subject devices are similar. In comparison to the butterfly geometry, the circular coils have just one coil element. This gives a better usability with no rotation limitation. All coils achieve the same intended use. The differences of the circular and butterfly geometries are negligible and do not raise new or different questions of safety and effectiveness.

CONCLUSION

Except for the indication for use, the subject device is identical to the previously cleared MagPro family device. Thus, software validation, electrical safety testing, and performance testing can be leveraged for this device. The similar indications for use, stimulation patterns, technological characteristics, and performance characteristics for the proposed *MagVenture Pain Therapy* are assessed to be substantially equivalent to the predicate device.