February 3, 2021

Lhasa OMS, INC.
c/o Saori Sawaki
Business Manager
Ken Block Consulting, LLC
800 E. Campbell Road, Suite 202
Richardson, Texas 75081

Re: K200636
Trade/Device Name: AXUS ES-5 Electro-Acupuncture Device
Regulatory Class: Unclassified
Product Code: BWK
Dated: December 31, 2020
Received: January 4, 2021

Dear Saori Sawaki:

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,

Pamela Scott
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)*
K200636

Device Name
AXUS ES-5 Electro Acupuncture Device

Indications for Use *(Describe)*
The AXUS ES-5 Electro Acupuncture Device is an electro-acupuncture device indicated for use in the practice of acupuncture by qualified professionals of acupuncture as determined by the states.

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.***

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*"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

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|---|---|---|
| Owner / Submitter: | Lhasa OMS, Inc.<br>230 Libbey Parkway<br>Weymouth, MA 02189 | |
| Contact Person: | Lhasa OMS, Inc.<br>Ms. Colleen Pike<br>President<br>230 Libbey Parkway<br>Weymouth, MA 02189<br>TEL: 781-340-1010, extension 11<br>FAX: 781-340-1637<br>mpikeoms@aol.com | |
| Date Prepared: | February 23, 2021 | |
| Submission Type: | Traditional 510(k) Submission | |
| Proposed Device: | 510(k) Number: | K200636 |
| | Trade Name: | AXUS ES-5 Electro-Acupuncture Device |
| | Common Name(s) | Electro-Acupuncture Stimulator |
| | Product Code: | BWK |
| | Device Class: | Unclassified |
| | Panel: | Neurology |
| Predicate Device: | 510(k) Number: | K081943 |
| | Trade Name: | ES-130 |
| | Common Name(s): | Electro-Acupuncture Stimulator |
| | Product Code: | BWK |
| | Device Class: | Unclassified (Pre-Amendment) |
| | Panel: | Neurology |

| | |
|---|---|
| Statement of Intended Use: | The *AXUS ES-5 Electro-Acupuncture Device (AXUS ES-5)* is an electro-acupuncture device indicated for use in the practice of acupuncture by qualified professionals of acupuncture as determined by the states. |
| Device Description: | The *AXUS ES-5* is an electro-acupuncture device indicated for use in the practice of acupuncture by qualified professionals of acupuncture as determined by the state. The *AXUS ES-5* is a battery operated prescription use only electro-acupuncture device used for applying electric stimuli to areas of preferred delivery (APD). The device uses a low-intensity, low-frequency pulse multimode generator through micro-alligator clips attached to commercially available and FDA-cleared stainless steel acupuncture needles. The device can also deliver stimulation with the included probe. |

It is recommended to use only commercially available FDA-cleared stainless steel acupuncture needles with a 0.20mm minimum diameter. When using the *AXUS ES-5* with Micro Alligator Clips, the clips should be connected to stainless steel acupuncture needles that penetrate the skin at the areas of preferred delivery (APD). Accessories that are included with the *AXUS ES-5* include four connecting cables in four colors with the industry standard 0.08 diameter pins, four Micro Alligator Clips on 0.08 pin socket cables, one handheld APD/STI Probe with grounding pole (handgrip), and one large and one small interchangeable tips to be used with the probe. Optional accessories include Alligator Clips, EZ-Grip Clips, Duck Beak Clips, Micro Hook Clips. The optional accessories are sold separately according to the client's specific needs but can be ordered with the *AXUS ES-5* from Lhasa OMS. The *AXUS ES-5* is provided non-sterile and does not require sterilization for use.

Summary of Technological Characteristics:

The *AXUS ES-5* electro-acupuncture device provides multiple functions and features five built-in output channels with a digital display panel. Four channels are normal output channels and are separated into two groups for adjusting frequency and pulse width.

The first and second channels comprise Group 1 and may be adjusted with the knobs on the left side of the device. The third and fourth channels comprise Group 2 and may be adjusted with the knobs on the right side of the device. Output intensity of the current can be adjusted individually for each channel by rotating the channel's corresponding knob clockwise to increase or counterclockwise to decrease intensity. The fifth channel is reserved for the probe, which incorporates an effective stimulation feature with a push button of 10 Hz.

The device features three LCD displays. The left LCD display shows the Channels 1 and 2 precise frequencies, and the right LCD display shows the Channels 3 and 4 precise frequencies. The middle LCD displays the output of the probe, which shows the resistance of the areas of preferred delivery on the skin and the precise frequency during direct stimulation.

The *AXUS ES-5* features three different operating stimulation modes, Continuous, Modulate, and Burst, and can operate on High and Low voltage with a switch for the output selection. The *AXUS ES-5* is equipped with a timer that has selections for 15 minutes, 30 minutes, and continuous sessions. When the timer setting ends, the device will turn off, but operation will resume after all channels are reset to the zero position. The panel features the ability to turn the buzzer on and off during APD mode. Additional information on the electro-acupuncture device can be found in the *AXUS ES-5* Instructions Manual.

The *AXUS ES-5* and the predicate device have identical waveform shapes (i.e., asymmetrical biphasic). Each pulse consists of an initial positive charge (overall rectangular shaped) followed by a negative charge (overall triangular shaped). As with the predicate device, the amount of charge is equal in both the positive portion and negative portion of each pulse, resulting in zero net charge per pulse. The maximum frequency, output voltage and output current for the X1 and X5 electric stimulation settings are all lower than the single setting for the predicate device. The maximum average power density of the *AXUS ES-5* is 35.7 mW/cm², which, along with the predicate device, is well below the FDA recommended maximum of 250 mW/cm². As

with the predicate device, the *AXUS ES-5* requires the special attention of the user because current density exceeds 2mA/cm$^2$.

Minor differences exist between the proposed device and the predicate device, but these minor differences do not have an impact on safety and efficacy. The *AXUS ES-5* and predicate device have different accessories, dimensions, and weight. This is common in the marketplace and does not impact the safety, effectiveness, or substantial equivalence of the device. The storage temperature of the *AXUS ES-5* device is 10˚C to 50˚C, while the ES-130 has a storage temperature of 10˚C to 60˚C. This difference does not impact safety or effectiveness because the storage temperature of the *AXUS ES-5* is within the range of the storage temperatures of the predicate device. The *AXUS ES-5* has a timer setting that allows the user to choose the duration of treatment (15 minutes, 30 minutes, and continuous sessions) while the predicate device do not offer this setting. This difference does not have an impact on performance or safety because this feature offers the option to limit the duration of operation and therefore exposure.

The information presented in the 510(k) supports the claim that the *AXUS ES-5* is substantially equivalent to the identified predicate device in design rationale, methodology of use, and performance.

Summary of Performance Testing:

The *AXUS ES-5* was developed and is produced under considerations of all applicable technical standards, internal specifications, and FDA guidance documents. The product's conformance with applicable international and internal standards was verified in the course of bench performance studies. In addition, the *AXUS ES-5* has been tested in accordance with applicable standards for medical device electrical safety, electromagnetic compatibility, and the particular requirements for safety and effectiveness. The *AXUS ES-5* Clips have been tested to meet the requirements of 21 CFR 898. Biocompatibility has been evaluated in accordance with ISO 10993-1. The *AXUS ES-5* output waveforms, basic unit characteristics, and output specifications are included in the 510(k) submission as indicated in the FDA guidance document "*Guidance for Industry, FDA Reviewers/Staff and Compliance - Guidance Document for Powered Muscle Stimulator 510(k)s"*.

Conclusion:

*Lhasa OMS* considers the *AXUS ES-5* to be substantially equivalent to the predicate device listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.