February 15, 2024

Neuro Spinal Innovation Inc
Madhava Tirukovela
Quality and Procurement Specialist
77 City Centre Drive, Suite 501, East Tower
Mississauga, ON L5B 1M5
Canada

Re: K234036
Trade/Device Name: SONIK MONARK 100
Regulatory Class: Unclassified
Product Code: LXM
Dated: December 20, 2023
Received: December 21, 2023

Dear Madhava Tirukovela:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Rehabilitation 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)*
K234036

Device Name
SONIK MONARK 100

Indications for Use *(Describe)*
The SONIK MONARK 100 device is to be used in the aid of management of chronic pain due to non-congenital defects. The device can be used as part of a series of steps in the total care of the patient. The procedure involves the use of diagnostic imaging that qualifies the misalignment between vertebrae. The treatment is then administered using the device to deliver precise impulses at a required vector configuration.

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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510(k) Summary

SONIK MONARK 100

1. Submitter Information

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Canada

Contact: Madhava Tirukovela
Tel: +1-323-412-5662
Email: regulatory@neuro-spinal.com

Date Prepared: February 2, 2024

2. Device Identification

Trade/Proprietary Name:	SONIK MONARK 100
Common/Usual Name:	Manipulator Device
Classification Name:	Manipulator, Plunger-like Joint
Regulation Number:	21 CFR 890
Product Code:	LXM
Class:	Unclassified
Unclassified Reason:	Pre-Amendment
510(k) #:	K234036

3. Legally Marketed Predicate Device(s)

Device name:	KKT-M2
510(k) number:	K130666
Manufacturer:	Optima Health Solutions International Corporation

4. Indication for Use Statement

The SONIK MONARK 100 device is to be used in the aid of management of chronic pain due to non-congenital defects. The device can be used as part of a series of steps in the total care of the patient. The procedure involves the use of diagnostic imaging that qualifies the misalignment between vertebrae. The treatment is then administered using the device to deliver precise impulses at a required vector configuration.

5. **Device Description**

The SONIK MONARK 100 (SM-100) device is used for the management of chronic pain due to non-congenital defects. It operates through the delivery of low-frequency impulses onto intact skin. The device converts electrical energy into mechanical energy, which is then transmitted to the patient's tissues through the stylus tip. It employs a mode of action that involves the application of controlled and repeatable low-intensity mechanical impulses to the treatment site. The device can be used in a handheld manner or mounted to a movable arm on a cart.

Table 1 – Comparison of Characteristics of the SONIK MONARK 100 and the KKT-M2

Characteristic			**Comparison**
Manufacturer	**Optima Health Solutions International Corporation**	**Neuro Spinal Innovation Inc.**	N/A
Trade Name	**KKT-M2**	**SONIK MONARK 100**	N/A
510(k) Number	**K130666**	**K234036**	N/A
Product code	LXM	LXM	Same
Regulation Number	Unclassified	Unclassified	Same
Regulation Name	Manipulator, plunger-like device	Manipulator, plunger-like device	Same
Indications For Use	The KKT device is to be used in the aid of management of chronic pain due to non-congenital defects. The device can be used as part of a series of steps in the total care of the patient. The procedure involves the use of diagnostic imaging that qualifies the misalignment between vertebrae. The treatment is then administered using the KKT - M2 device to deliver precise impulses at a required vector configuration.	The SONIK MONARK 100 device is to be used in the aid of management of chronic pain due to non-congenital defects. The device can be used as part of a series of steps in the total care of the patient. The procedure involves the use of diagnostic imaging that qualifies the misalignment between vertebrae. The treatment is then administered using the device to deliver precise impulses at a required vector configuration.	Same
Intended Use/ Operation of device	The KKT-M2 device is to be used in the aid of management of chronic	The SONIK MONARK 100 device is to be used in the aid of management of chronic	Same

	pain due to non-congenital defects.	pain due to non-congenital defects.	
Components (System)	Touchscreen Horizontal Arm Vertical Plate Base Plate Transducer Head Stylus	Touch Screen - - - Treatment Head Stylus	Different
Software	Contains Firmware	Contains Firmware	Same
Mechanical Characteristics			
Diameter	15mm	15mm	Same
Stylus material	Acrylic	Acrylic	Same
Stylus tip material	Elastosil R401/60	Elastosil R401/60	Same
Sterility	N/A	N/A	Same
Linear Motion of Stylus			
Distance	0.125 inches max	3.175 mm max (0.125 inches)	Same
Motion	Sinusoidal	Sinusoidal	Same
Frequency	16-80Hz	16-100Hz	Different
Force	5lbs maximum	17 N maximum (equivalent to 3.82 lbs)	Different
Cycles	User controlled	User controlled	Same
Rotational Motion of Stylus			
Angle	+/- 30deg max.	0 deg	Different
Direction	Clockwise, Counter-clockwise	Not Applicable; No Rotation	Different
Repetitions	Once per cycle	Not Applicable; No Rotation	Different
Limits	Electronic and mechanical stop	Not Applicable; No Rotation	Different
Positioning Base and Stand Adjustments			
Stylus Tip			
Vertical motion	Up to 3mm (1/8'') during treatment. Maximum travel from lowest to highest points of the vertical leadscrew is 26cm	Movement of 3 mm (1/8") during treatment.	Different
Horizontal transverse motion	Distance unit can travel along base plate rail along the transverse patient plane at least 50cm in each direction from centre point. Manual operation with adjustable friction brake	Not Applicable	Different

Horizontal axial motion	Arm extends/ retracts horizontally axially a total of 36cm. Motion is lead-screw driven, with braking mechanism incorporated into the lead screw controller.	Not Applicable	Different
Treatment Head/Armature Adjustments			
Horizontal motion	Horizontal motion	Not Applicable	Different
Angular motion	Angular motion	Not Applicable	Different
Device System			
Interface Transducer Head	Interface Transducer Head	Interface Transducer Head	Same
Display	LCD touchscreen display	LCD touch screen display	Same
Keypad	Keypad	Not Applicable	Different
Communications	USB serial	Bluetooth	Different
Mains Power supply	Mains power supply	Mains power supply	Same
Fuse, mains	Fuse, mains	Fuse, mains	Same
Fuse (for 24VDC transducer power)	1.6A 250VAC	Slowblo 48VDC 2A	Different
Environment	+15°C to +40°C 10%-90% RH (non-condensing)	+10°C to +35°C 30%-75% RH (non-condensing)	Different
Storage	-5°C to +35°C 10%-90% RH	-35°C to +55°C 10%-90% RH	Different
Weight	350 lbs	Device: Approx. 1000g Device + Accessories: Approx. 65kg	Different
Accessories			
Accessories (optional)	Start/Stop Motorized Bed Interface	Cart Arm Stylus Sleeve	Different

7. Substantial Equivalence Discussion

The SONIK MONARK 100 and KKT-M2 have identical indications for use. The devices are identical with respect to their material, the type of energy used by the device, and type of energy that is delivered by the device to the patient. Both devices generate similar frequency ranges and are applied to patients in a similar manner. Although differences exist between the designs of the two devices, comparison of

the SONIK MONARK 100 with the predicate KKT-M2 device indicate that the technological characteristics of the SONIK MONARK 100 are substantially equivalent to those of the predicate device.

Design/technological differences between the two devices predominantly relate to device portability. The KKT-M2 device requires a base plate, vertical stand, and arm to position the treatment head, whereas the SONIK MONARK 100 features a smaller, lighter treatment head that can be operated as a handheld device. When in use, the arm accessory of the SONIK MONARK 100 is able to be manually adjusted, rather than requiring the use of an adjusting keypad. The SONIK MONARK 100 communicates with the connected computer wirelessly via Bluetooth, whereas the KKT-M2 device communicates with the connected computer via a USB cable. The SONIK MONARK 100 differs from the KKT-M2 in that it does not have a rotatory component in the stylus. Finally, the maximal force threshold for the SONIK MONARK 100 device was decreased from that of the KKT-M2. Since the force applied during treatment is slightly lower than the maximal force threshold of the KKT-M2 device, this will not impact the respective safety or efficacy of the SONIK MONARK 100 in comparison to the KKT-M2 device. Analysis of these differences indicates no substantial effect on the safety or effectiveness of the SONIK MONARK 100 in comparison to that of the KKT-M2. Overall, the SONIK MONARK 100 does not raise any questions of safety or effectiveness compared to the predicate device. Consequently, the devices can be considered to be substantially equivalent.

8. **Performance Data**

Electrical Safety and Electromagnetic Compatibility (EMC)
The device has been successfully tested to the following standards by accredited testing laboratories for performance and safety testing.

#	Standard	Standard Title	Version	Date
1	IEC 60601-1	Medical Electrical Equipment – Part 1	Ed 3	Jun-19-2023
2	IEC 60601-1-2	Medical Electrical Equipment – Part 1-2	Ed 4.1	Sep-14-2023

Software Verification and Validation
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "General Principles of Software Validation." The software for this device was considered as a "Moderate" level of concern, since a failure or latent flaw in the software may, prior to mitigation of hazards, result in a Minor injury to patient or user, but this would not present a hazardous situation with a probable risk of death or serious injury to the patient, user, or others in the environment of use.

Vibration Frequency Verification

The study was conducted to verify the SONIK MONARK 100 accurately and reliably produces a sample of intended frequencies. For the intended frequencies that were tested, the frequencies produced by the device did not deviate from the target frequency by more than the acceptable margin of error (< 5 %).

These findings support the conclusion that the SONIK MONARK 100 device accurately and reliably produces vibration frequencies as intended. This outcome confirms the device's precision achieves its target performance specifications.

9. Discussion and Overall Conclusions

The SONIK MONARK 100 is substantially equivalent to the predicate KKT-M2 device in terms of its intended use, indications of use, operating principles, technological characteristics, and risk profile.

Both devices possess the same indications for use, operating principles, performance specifications, and safety features. Differences in the technological characteristics of the devices predominantly relate to portability. The technological characteristics of the SONIK MONARK 100, in comparison to those of the predicate device, do not raise any new questions of safety or effectiveness. In conclusion, the SONIK MONARK 100 device and the KKT-M2 device can be considered substantially equivalent devices.