April 27, 2022

UltraThera Technologies, Inc.
Kevin Maher
President
2 North Cascade Avenue, Suite 640
Colorado Springs, Colorado 80903

Re: K220231
Trade/Device Name: GyroStim
Regulatory Class: Unclassified
Product Code: LXV
Dated: January 26, 2022
Received: January 27, 2022

Dear Kevin Maher:

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,

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K220231

Device Name
GyroStim

Indications for Use *(Describe)*
The GyroStim is intended to assist in the treatment of balance disorders and vestibular dysfunction in adult patients, age 18 and older, up to 400lb. It is intended to be used by a trained medical professional as prescribed by physician in a clinical environment.

Restricted Device (per 21 CFR 801.420 and CFR 801.421).

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

1. Sponsor/ Applicant

UltraThera Technologies, Inc.
2 North Cascade Ave., Suite 640
Colorado Springs, Colorado 80903

Kevin Maher
President
Phone: (719) 685-7883
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Summary Preparation Date: January 26, 2022

2. Device

Trade Name	GyroStim
Model Numbers	V4-GYROSTIM III-04 - GyroStim G 1 – Stationary canopy, no laser option V4-GYROSTIM III-04 - GyroStim G 3 – Stationary canopy with laser target option V4-GYROSTIM III-04A - GyroStim G 3X – Sliding canopy with laser target option
Classification	Unclassified (pre-amendment)
Product Code	LXV
510(k) Number	K220231
Review Panel	Ear, Nose, and Throat (ENT) Devices

3. Predicate Device

Vesticon Epley Omniax™, 510(k) # K071973

4. Device Description

GyroStim is an AC powered computer-controlled multi-axial positional and rotational chair. The device consists of a patient chair mounted within a rotational frame assembly that is capable of rotating in the pitch and yaw axes. The rotational frames are automated with computer-controlled drive systems capable of executing pre-programmed positional and rotational motion profiles. The system provides clinicians with a safe and efficient means for administering a wide range of specific positional and rotational motions for inducing stimulation of the vestibular system.

GyroStim operational software runs on a pc-based desktop computer. The software can capture, monitor, and display the patient's subjective and objective response to each run. The response data may be used by the clinician for clinical decision support (CDS) to assist with progress evaluation, for profile selection and rate of therapy advancement, for individualizing therapy sessions, and for monitoring and preventing overstimulation.

Patient data is collected and stored and may be accessed for graphing, analysis, and reports.

The software includes libraries of prewritten profiles. A library of pre-written positional profiles located on the RUN BPPV page contains a collection of profiles for executing commonly used canalith repositioning maneuvers. A library of pre-written motion profiles located on the RUN GyroStim page contains a collection of profiles for executing motion induced vestibular stimulation.

Specifically, the library of motion profiles contains 30 levels of motion induced vestibular stimulation intensity, ranging from Level 1 to Level 30. The lowest level of motion induced vestibular stimulation intensity is Level 1, which rotates at a rate of 1 revolution per minute (RPM) or 0.016667 Hz. The highest level of motion induced vestibular stimulation intensity is Level 30, which rotates at 30 RPM or 0.5Hz. The intensity of the 30 levels differs and increments linearly at a rate of 1 RPM or 0.01667Hz per level; i.e., Level 1 rotates at 1 RPM or 0.01667 Hz, Level 2 rotates at 2 RPM or 0.03334 Hz, Level 3 rotates at 3 RPM or 0.05 Hz, and so on up to Level 30 which rotates at 30 RPM or 0.5 Hz. Additionally, each of the 30 Levels offer a selection of run durations at 15 seconds (s), 30s, 60s, and 180s.

When configured with the integrated patient transfer system, GyroStim provides accessibility to the large population of patients with moderate to severe mobility challenges, many of whom are limited or unable to engage in the existing standard of care for balance disorders and vestibular dysfunction.

The GyroStim assembly, operational software, and libraries of profiles provide clinicians with a safe, effective, and efficient medical device for assisting in the treatment of balance disorders and vestibular dysfunction.

5. Indications for Use

The GyroStim is intended to assist in the treatment of balance disorders and vestibular dysfunction in adult patients, age 18 and older, up to 400lb. It is intended to be used by a trained medical professional as prescribed by physician in a clinical environment.

6. Technological Characteristics and Substantial Equivalence

The GyroStim is substantially equivalent to the Epley Omniax regarding the intended use and technological characteristics, as explained in following table and discussion:

Feature	Subject Device UltraThera GyroStim	Predicate Device Vesticon Epley Omniax	Comparison of Devices
510(k) Number	K220231	K071973	N/A
Intended Use	The GyroStim is intended to assist in the treatment of balance disorders and vestibular dysfunction.	The Omniax is intended to assist in the diagnosis and treatment of balance disorders and vertigo, including benign paroxysmal positional vertigo	Comparable
Target patient population	Adults, age 18 and older, maximum 400lb	Adults, age 18 and older, maximum 350lb	Comparable
Use environment	Professional healthcare /	Professional healthcare /	Same

Feature	Subject Device UltraThera GyroStim	Predicate Device Vesticon Epley Omniax	Comparison of Devices
	clinical environment	clinical environment	
Delivery of Therapy	Whole body positioning and rotation	Whole body positioning and rotation	Comparable
Library of Profiles	Libraries of positional maneuvers and rotational profiles	Library of positional maneuvers	Comparable
Intended User	Trained medical personnel	Trained medical personnel	Same
Frequency of use	As prescribed by physician	As prescribed by physician	Same
Prescription and/or over-the-counter use	By prescription only	By prescription only	Same
Operator Interface	Computer with operational software to control the rotational and positional motion of the chair	Computer with operational software to control the rotational and positional motion of the chair	Same
Positional and Rotational Means	Electro-mechanical motion chair	Electro-mechanical motion chair	Same
Axis of Motion & Rotational Degrees	Pitch: 360º Yaw: 360º	Pitch, 360º Yaw, 360º Roll, 360º	Comparable
Maximum Acceleration	180 deg/s2	*(Information is redacted)*	Unknown
Maximum Velocity	180 deg/s (30 RPM)	*(Information is redacted)*	Unknown
Collects and reports patient response to vestibular stimulation	Yes	Yes	Same
Patient Restraint System	Five-point harness and interlocked lap and ankle restraints	Two parallel over-shoulder straps, lap belt	Comparable
Electrical Safety Performance	Complies with ANSI/AAMI/ES 60601-1, Ed 3.1 and applicable collateral standards	Complies with IEC 60601-1	Same
EMC	Complies with ANSI/AAMI/IEC 60601-1-2, Ed 4, Class A, professional healthcare environment	Complies with IEC 60601-1-2	Same

7. Non-clinical Bench (Performance) testing

The performance of the GyroStim is verified based on the successful completion of following tests:

Item Tested	Test Method	Purpose	Acceptance Criteria	Results
V4-GYROSTIM III-04A	ANSI/AAMI/ES 60601-1, Ed 3.1	Electrical safety	Complies with ANSI/AAMI/ES 60601-1, Ed 3.1	Pass
V4-GYROSTIM III-04A	ANSI/AAMI/IEC 60601-1-2, Ed 4	EMC	Complies with Class A, Professional Healthcare Environment of ANSI/AAMI/IEC 60601-	Pass

Item Tested	Test Method	Purpose	Acceptance Criteria	Results
			1-2, Ed 4	
V4-GYROSTIM III-04, V4-GYROSTIM III-04A	Engineering Analysis per Clause 9.8.2 and Table 21 of IEC 60601-1, Ed 3.1	Determination of static loading safety factors	Safety factor determined to be greater than the 2.5x requirements of Table 21 of IEC 60601-1	Pass, Min. safety factor, 27.5x
V4-GYROSTIM III-04, V4-GYROSTIM III-04A	Engineering Analysis	Determination of floor loading distribution for installation into non-residential environments	Complies with uniform and concentrated live load requirements per IBC, 2018*	Pass
V4-GYROSTIM III-04, V4-GYROSTIM III-04A	Engineering Analysis	Reliability analysis, including fatigue and dynamic loading, and retrospective data analysis	Device shall remain reliable and not cause patient or end user injury for 10-year shelf life	Pass
V4-GYROSTIM III-04, V4-GYROSTIM III-04A, GyroStim software	IEC 62304: 2006/A1:2016, clause 5.7 and FDA's Guidance for Industry and FDA Staff, "Guidance for the Content for the Premarket Submissions for Software Contained in Medical Devices".	Software verification	Software complies with pre-defined requirements of the software requirement specification for a Class B / "moderate" level of concern due to software failure	Pass
V4-GYROSTIM III-04, V4-GYROSTIM III-04A, GyroStim software	Measurement of rotational accuracy in pitch and yaw directions	Accuracy of Controls	System meets the defined accuracy requirements for RPM, acceleration, and degrees of rotation	Pass
V4-GYROSTIM III-04, V4-GYROSTIM III-04A,	IEC 62366-1, 2015 +A2020 and FDA's Guidance for Industry and FDA Staff, "Applying Human Factors and Usability Engineering to Medical Devices"	Summative Usability Study	No instances of use errors or close calls with potential for harm	Pass, none observed

8. Biocompatibility Testing

The biocompatibility evaluation for the GyroStim device was conducted in accordance with the FDA's Guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" September 2020, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

Overall, it can be concluded that the GyroStim materials in limited, direct, or transient patient contact with intact skin pose a very low biocompatibility risk based upon materials characterization, common use in healthcare and commercial applications, and history of safe use.

9. Clinical Testing

A preliminary clinical study was conducted to compare the outcomes of the RUN GyroStim profiles to outcomes of the current standard of care (SOC) for treatment of balance disorders and vestibular dysfunction. The study utilized retrospective data from the two treatment groups: GyroStim group, and SOC Group.

The clinical comparison included data from pre and post intervention assessments from both patient groups. The assessments and treatments were performed by a vestibular and balance medical specialist (DPT) and with quantitative equipment and methods, including SOT, DHI, ABC, DVA, and mDGI. Both groups received the same intake, balance education, and training for at-home daily exercise routines. The only variable between the two groups was the treatment: treatment with GyroStim, or treatment with SOC. Assessment data from multiple vestibular/balance disorders were collected retrospectively and presented for both groups.

Data comparison was conducted for both treatment groups to compare the following:

- difference in pre- and post- objective or subjective balance scores
- duration of treatment time between pre- and post- therapy balance scores

The analysis of retrospective clinical test data from patients with vestibular and balance disorder indicated that the RUN GyroStim profiles provided treatment that was as effective as the current SOC.

The retrospective data also indicated that treatment with RUN GyroStim profiles provided a statistically relevant ($p<0.0001$) average balance score improvement per week of treatment when compared to SOC. Overall, the preliminary clinical study indicated that treatment with GyroStim provided substantially equivalent treatment of vestibular/balance disorders as the current standard of care.

10. Conclusion:

The subject device, GyroStim, has a substantially equivalent intended use and technological characteristics as the cited predicate device. The minor changes or differences presented do not raise new questions of safety or effectiveness. The non-clinical test results have demonstrated the subject device is as safe and can perform with substantial equivalence as the predicate device. The preliminary clinical study provides evidence that the subject device is as effective as the current standard of care for balance disorders and vestibular dysfunction.

Therefore, it is concluded that no new questions of safety and effectiveness were raised. We conclude that the subject device is substantially equivalent to the cited predicate device.