TracInnovations ApS
% Sheila Pickering Ph.D.
Consultant
Sheila Pickering PhD
2081 Longden Circle
LOS ALTOS CA 94024

April 28, 2021

Re: K203451
Trade/Device Name: TCL3 Motion Tracking System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: April 8, 2021
Received: April 12, 2021

Dear Dr. Pickering:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
not known K203451

Device Name
TCL3 Motion Tracking System

Indications for Use *(Describe)*
The TCL3 Motion Tracking System is an accessory to a Magnetic Resonance Imaging (MRI) scanner. The system uses a markerless sensor based technology for tracking of patient movement during an MRI session. It provides the current position of the patient in real-time to the MRI scanner. The TCL3 System is intended to support, supplement and/or augment the performance of the Siemens Magnetom Skyra, Siemens Magnetom Prisma, Philips Achieva and GE Signa Premier scanners.

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 (K203451)
Prepared April 08, 2021

Sponsor:	TracInnovations World Trade Center, Borupvang 3, DK-2750 Ballerup Denmark
Contact Person:	Stefan Glimberg
Telephone:	+45 61 66 89 69
Submission Date:	November 18, 2020
Device Name:	TCL3 Motion Tracking System
Common Name:	Magnetic Resonance Diagnostic Device (MRDD)
Trade Name:	TCL3 Motion Tracking System

Classification:

Regulatory Class:	II
Review Category:	21CFR 892.1000 (LNH)
Classification Panel:	Radiology

A. Legally Marketed Predicate Devices

The predicate device is the Motion Correction System (K193324) manufactured by KinetiCor, Inc.

B. Device Description:

The TCL3 Motion Tracking System monitors the patient's head for the duration of the scan. It can be turned off between patient scans. While running, the TCL3 Motion Tracking System continuously scans the surface of the patient's head, producing high-resolution 3D surfaces consisting of thousands of individual points. A structured light technique is utilized, using the combination of a camera and an infrared light modulator to reconstruct 3D surfaces of the patient's head. Each second, 30 surfaces are created. Each of these surfaces is used for geometric alignment relative to an initial reference position obtained at the beginning of the scan. From these alignments, motion data can be calculated in real-time.

C. Intended Use / Indications for Use

The TCL3 Motion Tracking System is an accessory to a Magnetic Resonance Imaging (MRI) scanner. The system uses a markerless sensor based technology for tracking of patient movement during an MRI session. It provides the current position of the patient in real-time to the MRI scanner.

The TCL3 System is intended to support, supplement and/or augment the performance of the Siemens Magnetom Skyra, Siemens Magnetom Prisma, Philips Achieva and GE Signa Premier scanners.

D. Substantial Equivalence

The TCL3 Motion Tracking System is substantially equivalent to the KinetiCor Motion Correction System (K193324).

Table 1. Substantial Equivalence Comparison of Indications for Use

Device Name	**Predicate Device** **Motion Correction System manufactured by KinetiCor (K193324)**	**Subject Device** **TCL3 Motion Tracking System manufactured by TracInnovations**
Indications for Use	The Motion Correction System is an accessory to a Magnetic Resonance Imaging (MRI) scanner. The system is a sensor based technology for tracking of patient movement during an MRI session. It provides the current position of the patient in real-time to the MRI scanner for further data processing. User: Professional Use Environment: Hospital, doctor's office, or any facility that uses an MRI device. KinetiCor defines the Motion Correction System as an accessory to a medical device. It is intended to support, supplement and/or augment the performance of the MAGNETOM Skyra 3T MRI scanner.	The TCL3 Motion Tracking System is an accessory to a Magnetic Resonance Imaging (MRI) scanner. The system uses a markerless sensor based technology for tracking of patient movement during an MRI session. It provides the current position of the patient in real-time to the MRI scanner. The TCL3 System is intended to support, supplement and/or augment the performance of the Siemens Magnetom Skyra, Siemens Magnetom Prisma, Philips Achieva and GE Signa Premier scanners.
Intended Users	Professional Use Environment: Hospital, doctor's office, or any facility that uses an MRI device.	Professional Use Environment: Hospital, doctor's office, or any facility that uses an MRI device.
Manufacturer	KinetiCor, Inc	TracInnovations
Regulation medical specialty	Radiology	Radiology
Product code	LNH	LNH
Regulation number	892.1000	892.1000
Regulation description	Magnetic resonance diagnostic device	Magnetic resonance diagnostic device
Classification	II	II

Table 2. Substantial Equivalence Comparison for Technological Characteristics

	Predicate Device: KinetiCor, Motion Correction System (K193324)	**Subject Device: TracInnovations, TCL3 Motion Tracking System**
Core Technology	KinetiCor defines the Motion Correction System as an accessory to a medical device. It is intended to support, supplement and/or augment the performance of the scanners indicated below.	TracInnovations defines its TCL3 Motion Tracking System as an accessory to a medical device. It is intended to support, supplement and/or augment the performance of the scanners indicated below.
Marker required	Yes. Requires attachment of marker to the nose bridge of the patient	No. Attachment of a marker is not required
Data acquisition sensor	Use at least two cameras out of four to identify a marker and then track the marker. Use infrared light to illuminate the marker.	Use one camera and one infrared light modulator (projection of structured light patterns) to identify and track a surface.
Line of sight	Line of sight for two cameras to the marker	Line of sight for the camera and infrared light modulator to the patient
MRI scanner compatibility	Siemens MAGNETOM Skyra 3T	Siemens MAGNETOM Prisma 3T Siemens MAGNETOM Skyra 3T Philips Achieva 3T GE Signa Premier 3T
Scanner bore compatibility	60 cm and 70 cm bore systems	60 cm and 70 cm bore systems
Scanner mounting	In-bore attachment, Fixed	Attachment on the scanner table, Detachable
Communication with scanners	Ethernet connection	Ethernet connection, UDP/IP protocol
Powering	Plug-in	Battery, >8 hours
Motion tracking	Tracks motion of the head in 6 degrees of freedom (x,y,z translations, and rotations)	Tracks motion of the head in 6 degrees of freedom (x,y,z translations, and rotations)
Translational accuracy	100 µm	200 µm
Rotational accuracy	0.1 degrees	0.2 degrees
Recording rate	60 frames per second	30 frames per second
Cross calibration procedure	At least once per month	Iteratively adapting

Based on the comparison of indication for use and technological characteristics, the subject device is substantially equivalent to the predicate device. Based on the performance data provided in the submission the differences do not introduce new issues related to safety and efficacy.

E. Performance Data

Each specification of the TCL3 Motion Tracking System has been verified and validated as required by the risk analysis. All design verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

The verification and validation testing included testing to the following applicable standards:

ISO 14971	Application of risk management to medical devices
IEC 60601-1	Medical electrical equipment- General requirements for basic safety and essential performance
IEC 60601-1-2	Electromagnetic disturbances
IEC 62304	Medical device software - Software life-cycle processes

Verification and validation testing were completed in accordance with the company's Design Control process in compliance with 21 CFR Part 820.30. Successful results for the following tests were included in the submission as performance data supporting substantial equivalence:

1. Bench testing for electrical and mechanical safety in compliance with the standards cited above
2. Bench testing for EMC in compliance with the standard cited above
3. Software testing, consisted of verification and validation testing in compliance with ISO 62304, including test cases related to off the shelf software, as well as cybersecurity features and wireless coexistence.
4. Bench testing for tracking quality and accuracy, MR compatibility and Mechanical compatibility

Clinical data was not required for this type of device.

F. Conclusion

Potential risks were identified according to the ISO 14971 Standards. The risks were analyzed with regard to risk/benefit category and mitigations were implemented and tested as part of the performance testing described above. All risk mitigations were satisfactorily verified and validated. Where there were technological differences from the predicate, the performance data demonstrated that these did result in any new issues of safety or efficacy.

Therefore, the TCL3 Motion Tracking System is substantially equivalent to the predicate device with regards to intended use and technological characteristics. Results of performance testing demonstrated that the device met the design requirements and as well as the user needs.