KinetiCor, Inc.
% Mr. Scott R. Herr
Sr. Director - RA/QA
3465 Waialae Avenue, Suite 300A
HONOLULU HI 96816

February 4, 2020

Re: K193324
Trade/Device Name: Motion Correction System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: November 27, 2019
Received: December 6, 2019

Dear Mr. Herr:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193324

Device Name
Motion Correction System

Indications for Use *(Describe)*
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.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act 1990 and 21 CFR Section 807.92.

1. **General Information**

Establishment: KinetiCor Inc.
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San Diego, CA 92131
Phone: (858) 800-1025
E-mail: www.kineticor.com
Registration Number: TBD

Date Prepared: November 27, 2019; Minor update January 30, 2020

Manufacturer: KinetiCor, Inc.
3454 Waialae Avenue, Suite 300A
Honolulu, HI 96816
Phone: (808) 800-1025

2. **Contact Information**

Scott R. Herr
Sr. Director - RA/QA
9965 Businesspark Ave., Suite B
San Diego, CA 92131
Phone: (858) 800-1025
E-mail: scott.herr@kineticor.com

3. **Device Name and Classification**

Device Name:	Motion Correction System
Trade Name:	Motion Correction System
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR Sec. 892.1000
Classification:	Class II
Product Code:	Primary: LNH

4. Legally Marketed Predicate Device (21 CFR §807.92(a)(3))

Trade Name:	MAGNETOM Vida
510(k) Number:	K183254 cleared January 18, 2019
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR Sec. 892.1000
Classification:	Class II
Product Code:	Primary: LNH, Secondary: LNI, MOS

5. **INDICATIONS FOR USE** (21 CFR §807.92(a)(5))

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.

6. Device Description (21 CFR §807.92(a)(4))

During an MRI scan, if the patient's head does not remain still during the scan, the resulting images may not be sharp. This could prevent a physician from analyzing the images, therefore requiring additional scanning.

Software has been developed to somewhat reduce these effects.

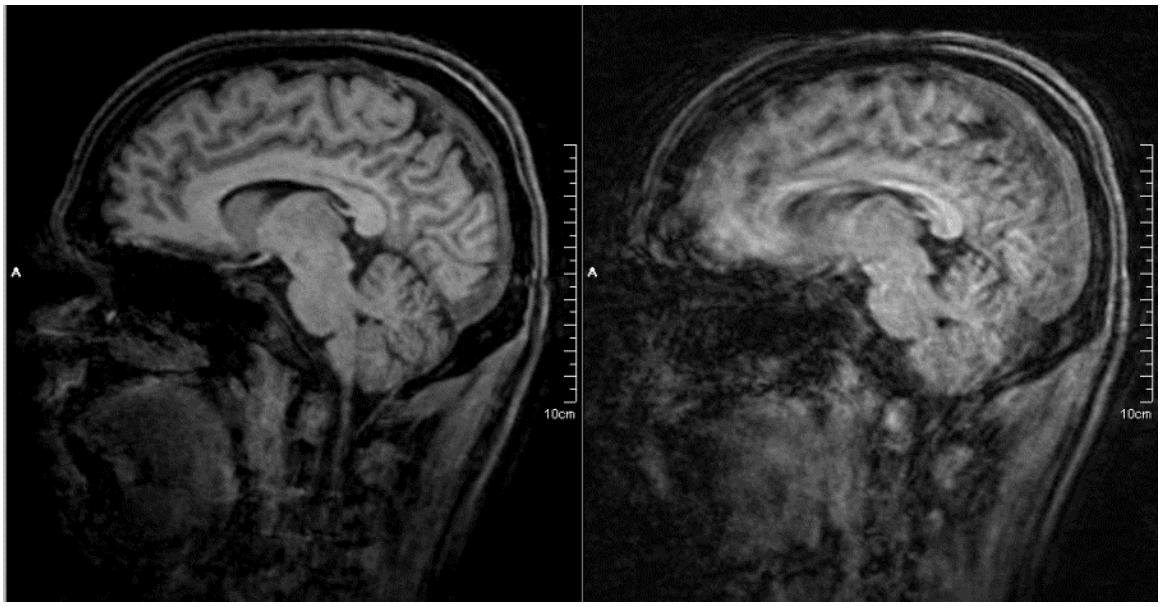
KinetiCor has developed a Motion Correction technology using a tracking device to track the true position of the patient's head. These coordinates are provided to the MRI scanner, which adjusts the MR images.

The Motion Correction System delivers head pose tracking and correction in 6 degrees of freedom for MR applications.

- Optimized for high field MR environments, the technology has been FDA Cleared for use in the MAGNETOM Vida, 510(k) K183254, cleared January 18, 2019. Customized optics, electronics and

enclosures minimize Electromagnetic Interference (EMI) and Radiofrequency (RF) interference and isolate the camera system for stable tracking accuracy.

- Proprietary optical machine vision motion tracking technology provides tracking data to the MRI scanner with a static accuracy of approximately 0.1 mm and 0.1 deg. This means that the MR pulse sequences are updated in real-time.
- The impact of the Motion Correction technology can be illustrated by taking a closer look at the corrected and uncorrected images in the figure below.



(a) (b)

(a) Motion correction using KinetiCor technology and (b) MR images obtained when the motion was not corrected and acquired using the conventional way. Similar motion performed during both scans.

KinetiCor is offering this accessory to the following MRI scanners that are installed in the field:

- Siemens MAGNETOM Skyra 3T (510(k) K153343 cleared April 15, 2016)

Hardware

The Motion Correction System Hardware consists of the following:

- Camera Enclosure (incorporating four Cameras) - located inside the distal end of the MRI scanner;
- Wiring Conduit - provides a protected location for wiring to exit the distal end of the MRI scanner;
- Processing Unit - electronics with software, located outside the MRI room;
- External Wiring - used to connect processing unit to Camera Enclosure;
- Tracking Markers - single use markers located on patient nose bridge (Referred to as “Nose Marker for Inline Motion Correction” in predicate device);
- External Monitor - if requested, located inside MRI Control Room;

- Network System - located outside the MRI room.

7. RISK MANAGEMENT, GENERAL SAFETY AND EFFECTIVENESS

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device. The Motion Correction System has an own Instruction for Use.

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by design means, protection measures and user instructions. To confirm that the measures are effective and that the product meets its intended uses, verification of requirements and standards, and validation of the clinical workflow was performed. KinetiCor adheres to recognized and established industry practice and relevant international standards where indicated.

8. Technological Characteristics and substantial equivalence (21 CFR §807.92(a) (6))

The KinetiCor Motion Correction System is substantially equivalent to the predicate device as the Camera Enclosure, Processing Unit electronics, Motion Correction Software and Tracking Markers are the same as in the predicate device. The camera enclosure, electronics and software for the MAGNETOM Vida are installed at the Siemens Factory on a new device prior to first customer use, whereas the KinetiCor Motion Correction System accessory is installed on the MAGNETOM Skyra 3T System, which is already in the field and in use.

While there are some differences in characteristics between the subject device and predicate device, including off-the shelf software applications (XPACE), wiring conduit configuration, external wiring, and external monitor; these differences have been tested and the conclusions from the non-clinical data suggests that the features bear an equivalent safety and performance profile to that of the predicate device.

9. Nonclinical Tests

The following performance testing was conducted on the subject accessory to a medical device:

- Software Verification and Validation testing was performed in accordance with FDA guidance document ”Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” dated May 11, 2005 and KinetiCor Quality System Procedure QSP-106 Quality Lifecycle Procedure.

- Design Verification and Validation testing was performed in accordance with 21 CFR 820 and KinetiCor Quality System Procedure QSP-102 Design Control.

10. Substantial Equivalence

There are very few differences between the KinetiCor Motion Correction System installed on a Skyra MRI and the predicate – almost all are due to the installing the KinetiCor accessory as a retrofit to existing product in the field versus assembly of the KinetiCor accessory at the factory in a brand new MAGNETOM Vida scanner.

The KinetiCor Motion Correction System as an accessory to a medical device is substantially equivalent to the MAGNETOM VIDA with software *syngo* MR XA11B and KinetiCor's Motion Correction accessories, which was 510(k) cleared on January 18, 2019 (K183254). As stated in that submission, "TFL with inline Motion Correction: Tracking of motion of the head during 3D MPRAGE head scans with a nose marker and a camera system. The MR system uses the tracking information to compensate for the detected motion." In fact, the designs of the nose marker, electronics and the camera enclosure system are the same as in the MAGNETOM Vida and the KinetiCor Motion Correction System.

11. Conclusions (21 CFR §807.92(b)(3))

The KinetiCor Motion Correction System as an accessory to a medical device provides the same motion correction hardware and technology as the predicate device system. The KinetiCor Motion Correction System provides motion correction features to potentially improve the magnetic resonance image if patient movement occurs during one specific sequence. It is a currently a feature in the predicate new device and a proposed accessory to an existing device.

KinetiCor believes that the Motion Correction System as an accessory to a medical device is substantially equivalent to the currently marketed device MAGNETOM VIDA with software *syngo* MR XA11B and KinetiCor's Motion Correction accessories.

The subject device does not raise any new questions with respect to safety or effectiveness. The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section.