March 7, 2019

Scientific Analytics, Inc.
% Evan Phelps
Principal
OFW Law
600 New Hampshire Ave., NW Suite 500
Washington, District of Columbia 20037

Re: K180880
Trade/Device Name: DARI Health
Regulation Number: 21 CFR 890.5360
Regulation Name: Measuring Exercise Equipment
Regulatory Class: Class II
Product Code: LXJ
Dated: December 18, 2018
Received: December 18, 2018

Dear Evan Phelps:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
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)*
K180880

Device Name
DARI Health

Indications for Use *(Describe)*
DARI Health is a computer and video system used to quantify and graphically display human movement patterns and techniques for uses such as assessment and training of limb or body motion in pre/post rehabilitation evaluation, physical therapy, and the like.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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"
As required by section 807.92(c)
For
DARI Health

February 4, 2019

1. Company Name and Address

   a. Sponsor/Manufacturer

Scientific Analytics, Inc.
2100 Magnum Circle
Suite 7
Lincoln, NE 68522

   b. Consultant/Contact

Evan P. Phelps
OFW Law
600 New Hampshire Ave, Ste. 500
Washington D.C. 20037
ephelps@ofwlaw.com
Tel: (202) 789-1212
Fax: (202) 234-3550

2. Establishment Registration Number: Not yet assigned

3. Device Name:

   a. Trade Name: DARI Health
   b. Common/Usual Name: Motion Measurement System
   c. Classification Name: System, Optical Position/Movement Recording

4. Device Classification:

    a. 21 C.F.R. § 890.5360 (Class II)
    b. Product Code: LXJ
    c. Classification Panel: Physical Medicine

5. Legally Marketed Predicate Devices:

    a. Peak Motus Motion Measurement System
        i. 510(k) Owner: Peak Performance Technologies, Inc.
        ii. 510(k) Number: K030714
        iii. 21 C.F.R. § 890.5360 (Class II)
        iv. Product Code: LXJ

6. Device Description

DARI's existing motion capture technology system has been utilized in non-clinical biomechanical research, fitness applications, and performance evaluation for many years. In view of experience with this technology, its numerous uses, and its demonstrated value, there is a need for the development of its use in clinical applications.

DARI Health is a "markerless," three-dimensional human motion capture and analytical software system that uses off-the-shelf video cameras, off-the-shelf computer hardware, off-the-shelf motion analysis software, and proprietary DARI Health Software (consisting of DARI Connect, DARI Capture plug-in, DARI Insight Engine, and DARI Report Engine) to collect, quantify, and document full-body human kinematics and kinetics during patient movement.

Motions are recorded in real-time, using a digital "skeleton" to identify joint center and segment data for the cervical spine, upper extremity, trunk, and lower extremity of the patient. The captured video can be viewed after recording has ended or at some later point.

During movement, the DARI Health interfaces with the capture software (off-the-shelf, *Captury Live*) tracks all segments and joint centers as they move in all planes of motion. The resulting output is sent to The DARI Insight Engine processing software—either housed locally on the computer used for capture or in a security-compliant, cloud-based server—where the data can be used to calculate all kinematic and kinetic data produced during the recorded motion. Such data is then displayed in different report formats—from large, raw datasets to simple, graphical reports that track key biomechanical metrics.

Healthcare providers can access patient biomechanical data remotely through a secure web-portal or locally on the computer database application to monitor patient progress and view prior or current motion analyses.

There is no direct contact with the patient by the DARI Health system, and no energy is delivered to the subject at any point during the usage of the system.

7. Intended Use

DARI Health is a computer and video system used to quantify and graphically display human movement patterns and techniques for uses such as assessment and training of limb or body motion in pre/post rehabilitation evaluation, physical therapy, and the like.

8. Technological Characteristics and Substantial Equivalence Evaluation

The technological characteristics of the DARI Health System device are based on the capture of three-dimensional motion information obtained from the subject under study. The video feed from the patient in motion is then recorded and stored on a computer where it is available for analysis of human motion using the DARI Health product. The DARI Insight Engine provided by DARI Health is used for data presentation to the healthcare professional. The data are accessible from a remote, security-compliant server for remote evaluations by the healthcare professional.

The DARI Health is substantially equivalent in terms of intended use, operating principles, and operational specifications to the Peak Motus Motion Measurement System (K030714) which is a legally marketable Optical Position/Movement Recording Systems classified pursuant to 21 C.F.R. §890.5360 under Product Code LXJ. As with the Peak Motus device, the DARI Health is intended to be used to quantify, analyze, document for remote access, visually display three-dimensional human kinematics, kinetics, and patient performance metrics related to human movement patterns for uses such as assessment and training of limb or body motion in applications where such analysis is relevant to the clinician's decision-making processes.

This equivalency is summarized in the Tables below where Table 1 discusses the equivalency of the indications for use between the DARI device and the predicates. Table 2 discusses the technological characteristics between the DARI device and the predicates to demonstrate substantial equivalency.

Substantial Equivalence to Predicate Devices Table 1: Indications for Use		
	Peak Motus K030714	DARI Health
Indications for Use	Computer and video system used to quantify and graphically display human movement patterns and techniques for uses such as assessment and training of limb or body motion in gait analysis, prosthetic design, pre/post rehabilitation evaluation, physical therapy, and the like.	DARI Health is a computer and video system used to quantify and graphically display human movement patterns and techniques for uses such as assessment and training of limb or body motion in pre/post rehabilitation evaluation, physical therapy, and the like.

Table 2: Technological Characteristics Comparison		
	Peak Motus K030714	DARI Health
Motion Capture	Optical cameras	Optical cameras
Principles of Operation	Software/Hardware system that uses off-the-shelf cameras, sensors, and computers to collect, quantify, and document human movement in two-dimensional or three-dimensional space. This system tracks and provides visual feedback of patient movement while reporting on kinematic parameters such as velocity and joint angles measured during movement	Use of off-the-shelf optical cameras or motion sensing technology, and computing equipment as the user interface and software, to collect, quantify, and document human movement in three-dimensional space. The DARI Health calculates such outputs as validated biomechanics and perforamce metrics vis cloud-based or local processing software.
Analysis and Interface Tools	Peak Motus uses software modules (Vicon) to capture, calculate, and represent patient biomechanical data	DARI Health uses software modules to capture, calculate, and display patient biomechanical data, and offers remote access to prior analyses via web-based portal and database.
Software and Hardware Compatibility	Peak Motus uses software and hardware that are compatible with Microsoft Windows	DARI Health hardware and software are compatible with Linux operating systems.
Operating System	Microsoft Windows	Linux-based OS
Markerless Motion Live Capture and Post-Processing	Live capture video requires use of position markers on subject's body. Post-processing motion analysis may be done without position markers on body.	DARI Health provides live markerless motion capture of the subject and the ability to post-process video for motion analysis. No position markers required for live capture or post-processing analysis.
Trajectory Reconstruction	2D and/or 3D reconstruction	3D reconstruction

Kinetic Calculations	Requires integration with force plates to measure kinetic data such as ground reaction force.	DARI Health uses subject and digital skeleton data to perform ground reaction force calculations.
External Measurement Device Integration	Electromyography (EMG) integration. Event synchronization units. Analog-to-digital interface (64 sensors)	None
Contraindications	None	None
Electrical Safety: Energy Used / Delivered	No energy is delivered to the patient	No energy is delivered to the patient
Biocompatibility	Not applicable	Not applicable
Mechanical, Thermal, Chemical Safety	Safety not an issue per 510k summary	No thermal, chemical, or safety issues during DARI Health motion analysis
Radiation Safety	System does not emit radiation	System does not emit radiation
Electromagnetic Compatibility	EMC and EMI Compliant	EMC and EMI Compliant
Sterility	Non-sterile device	Non-sterile device

9. Summary of Performance Data

DARI Health performance characteristics have been verified by independent, peer-reviewed studies proving the accuracy of the system's calculations of human kinematics and kinetics as compared to both traditional, gold-standard marker-based analysis and force plate output. Likewise, DARI Health internal studies demonstrate repeatability metrics that meet or exceed predicate and motion analysis industry standards. In addition, software validation and testing were completed for the device and functioned as intended and all results observed were those expected.

a. Non-Clinical Performance Summary

Safety

DARI Health utilizes common technical equipment to execute motion analysis with demonstrated safety. The system requires no contact with the patient, and poses no electrical, chemical, mechanical, thermal, or radiation safety concerns; therefore, there are

no safety issues associated with its use. The DARI Health complies with IEC 60601-1 and IEC 60601-1-2.

Effectiveness

Bench testing demonstrates the DARI Health motion capture methodology's accuracy in representing and tracking digital skeletal segments.

b. Clinical Performance Summary

Effectiveness

Clinical studies demonstrate the equivalency to predicate marker-based capture of human kinematics and industry-standard force plate output for evaluation of human kinetics.

Specifically, when compared to a predicate marker-based Vicon (Peak Motus) system in an independent, peer-reviewed study, the DARI Health system showed no statistically significant differences in the clinically relevant joint angles being measured for investigation ($p = 0.33$).

The DARI Health system was also tested against standard force plate output in an independent, peer-reviewed study, where DARI's force calculation methodology demonstrated no statistically significant differences in peak force, mean force, or low force as compared to simultaneous measurements derived from a force plate ($p > 0.05$). Additionally, comparison of force-time curves with regression yielded excellent correlation between modalities ($r = 0.995$, $r^2 = 0.989$, SEM = 11.1 N).

A clinical study also supports the repeatability of the DARI Health System.

Specifically, the repeatability of segment length and joint center calculation over successive scans of 9,120 bone segments demonstrated the ability to identify the joint centers and segment lengths within 0.811mm with 99% confidence, exhibiting only 1.02% total skeletal change between sessions with 0.002 mm of variance. This exceeds predicate repeatability associated with marker analysis and inter-test repeatability of goniometers claimed by predicate JRS v2.0.

10. System Validation for Software Design, Documentation, and Hazard Analysis

The DARI Health software is of "moderate" level of concern based upon FDA *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (2005). Consistent with FDA guidance and other applicable requirements, all hazards have been mitigated through appropriate controls, product labeling, while maintaining sufficient security measures to protect the software and data.

The DARI Health motion analysis software underwent a standardized approach consistent with the requirements of the Quality System Regulation (21 C.F.R. § 820.30) and ANSI 62304 for appropriate design, risk assessment, document, and validation control for software classed as "moderate level of concern."

DARI Health conforms to the following FDA recognized standards and associated FDA guidance documents:

- Medical Device Software-Software Life Cycle Processes ANSI/AAMI/ IEC 62304: 2006 & A1:2016
- Guidance on the use of AGILE practices in the development of medical device software AAMI TIR45:2012

11. Substantial Equivalence Conclusion

The aforementioned testing dominstrate substantial equivalence between the DARI Health System and the Peak Motus Motion Measurement System (K030714).