MEDO DX Pte. Ltd. (O/A MEDO.ai)
% Dornoosh Zonoobi
CEO and Co-founder
32 Carpenter Street 059911
SINGAPORE

June 11, 2020

Re: K200356
Trade/Device Name: MEDO ARIA
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QIH
Dated: May 7, 2020
Received: May 8, 2020

Dear Dornoosh Zonoobi:

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)*
K200356

Device Name
MEDO ARIA

Indications for Use *(Describe)*
MEDO ARIA is designed to view and quantify ultrasound image data using machine learning techniques to aid trained medical professionals in diagnosis of developmental dysplasia of the hip (DDH). The device is intended to be used on neonates and infants, aged 0 to 12 months.

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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"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."

K200356

Section 5. 510(k) Summary

5.1 General Information

510(k) Sponsor	MEDO Dx Pte. Ltd. (O/A MEDO.ai)
Address	32 CARPENTER STREET SINGAPORE 059911
Correspondence Person	Dornoosh Zonoobi
Contact Information	780-991-9462 dornoosh@medo.ai
Date Prepared	May 7, 2020

5.2 Proposed Device

Proprietary Name	MEDO ARIA
Common Name	ARIA
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Product Code	QIH
Regulatory Class	II

5.3 Predicate Device

Proprietary Name	QLAB Advanced Quantification Software
Premarket Notification	K191647
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Product Code	QIH
Regulatory Class	II

5.4 Device Description

MEDO ARIA is a cloud-based standalone software as a medical device (SaMD) that helps qualified users with image-based assessment of developmental hip dysplasia (DDH) of pediatric patients (e.g., ages 0 to 12 months). It is designed to support the workflow by helping the radiologist to evaluate, quantify, and generate reports for hip images.

MEDO ARIA Software takes as an input imported Digital Imaging and Communications in Medicine (DICOM) images from ultrasound scanners and allows users to upload, browse, and view images, measure alpha angle and acetabular coverage, and manipulate 2D and 3D infant hip ultrasound images, as well as create and finalize examination reports. It provides users with a specific toolset for viewing pediatric ultrasound hip images, placing landmarks, and creating reports.

Key features of the software are:

- 2D image visualization including one or more image frames that may have a spatial or temporal relationship
- Slice-scroll (frame scroll)
- Manual and semi-automatic landmark placements
- Alpha and coverage measurements
- Hip Graf classification
- Report generation

5.5 Indications for Use

MEDO ARIA is designed to view and quantify ultrasound image data using machine learning techniques to aid trained medical professionals in diagnosis of developmental dysplasia of the hip (DDH). The device is intended to be used on neonates and infants, aged 0 to 12 months.

5.6 Comparison of Technological Characteristics with the Predicate Device

Feature/ Function	**Subject Device** MEDO ARIA	**Predicate Device** QLAB Advanced Quantification (K191647)
Image input	Complies with DICOM Standard	Complies with DICOM Standard
Scan type	2D and 3D Ultrasound	2D and 3D Ultrasound
Image display mode	Static	Static
Image navigation and manipulation tools	Adjust image brightness and contrast, slice-scroll, pane layout, reset	Adjust image brightness and contrast, slice-scroll, pane layout, reset

2D image review	Yes, capable of reviewing all frames of multi-frame (multi-slice) image	Yes
Manual landmark placement	Yes	Yes
Semi-automatic landmark placement	Yes, user-modifiable	Yes, user-modifiable
Quantitative analysis	▪ Angle (alpha angle) ▪ Distance ratio (coverage)	▪ Distance ▪ Area
Lookup-table-based Graf Classification	Yes, user-modifiable	No
Report creation	Yes	No

5.7 Performance Data

Safety and performance of MEDO ARIA have been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Additionally, the software validation activities were performed in accordance with *IEC 62304:2006/AC:2015 - Medical device software – Software life cycle processes,* in addition to the FDA Guidance document, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."*

5.8 Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics, and performance testing, MEDO ARIA raises no new questions of safety or effectiveness and is substantially equivalent to the predicate device in terms of safety, efficacy, and performance.