MEDO DX Pte. Ltd.
Dornoosh Zonoobi
CEO and Co-founder
4560 TEC Centre, 10230 Jasper Avenue
Edmonton, Alberta T5J4P6
Canada

April 23, 2021

Re: K203502
Trade/Device Name: MEDO-Thyroid
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: QIH
Dated: March 22, 2021
Received: March 24, 2021

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

801and Part 809); 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)*
K203502

Device Name
MEDO-Thyroid

Indications for Use *(Describe)*
MEDO-Thyroid is designed to view and quantify ultrasound thyroid image data using machine learning techniques to aid in analysis of thyroid lobes and identify thyroid nodules, including evaluation, quantification and documentation of any such nodule. The device is intended to be used on adult patient images of 18 years or older.

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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Section 5. 510(k) Summary

5.1. General Information

510(k) Sponsor	MEDO DX Pte. Ltd. (O/A MEDO.ai)
Address	MEDO DX Pte. Ltd. (O/A MEDO.ai) 32 Carpenter Street, Singapore 059911
Correspondence Person	Dornoosh Zonoobi
Contact Information	780-991-9462 dornoosh@medo.ai
Date Prepared	November 20, 2020

5.2. Proposed Device

Proprietary Name	MEDO-Thyroid
Common Name	MEDO-Thyroid
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
Common Name	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-Thyroid is a cloud-based standalone software as a medical device (SaMD) that helps qualified users with image-based assessment of thyroid ultrasound images in adult patients of 18 years and older. It is designed to support the workflow by helping the radiologist to evaluate, quantify, and generate reports for thyroid ultrasound images.

MEDO-Thyroid 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 thyroid lobes and thyroid nodule volumes of single frame and multi-frame ultrasound images, as well as create and finalize examination reports. It provides users with a specific toolset for viewing ultrasound Thyroid images, placing landmarks, and creating reports.

Key features of the software are:

- Single and multi-frame visualization
- Cross Referencing
- Manual and semi-automatic landmark placements
- Thyroid Lobes (left and right) and thyroid nodule volume measurements
- TI-RADS Score and Classification (based on user manual input)
- Report generation

5.5. Indications for Use

MEDO-Thyroid is designed to view and quantify ultrasound thyroid image data using machine learning techniques to aid in analysis of thyroid lobes and identify thyroid nodules, including evaluation, quantification and documentation of any such nodule. The device is intended to be used on adult patient images of 18 years or older.

5.6. Comparison of Technological Characteristics with the Predicate Device

Feature / Function	**Subject Device** MEDO-Thyroid	**Predicate Device** QLAB Advanced Quantification (K191647)
Image input	Complies with DICOM Standard	Complies with DICOM Standard
Scan type	2D, 2D Cine, and 3D Ultrasound (Sing and Multi frame images)	2D, 2D Cine, 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
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	• Volume (thyroid lobes and user-identified thyroid nodules • Distance	• Distance • Area
TI-RADS Classification (based on user manual input)	Yes, based on ACR Standard guidelines and user manual input	No
Cross Referencing	Yes	No
Report creation	Yes	No

5.7. Performance Data

Safety and performance of MEDO-Thyroid 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."*

MEDO Thyroid-AI has been primarily trained and tested on the Philips, GE and Siemens ultrasound devices. The device has been tested using images acquired from the following ultrasound machines using high frequency linear transducers as described in Table 5.7.1 (below):

Table 5.7.1: Breakdown of ultrasound machines used for testing

Ultrasound Manufacturer	Machine
Philips	EPIQ 5G
	iU22
	CX50
GE	LOGIQE9
Siemens	S2000

Tables 5.7.2 and 5.7.3 (below) provide detailed breakdowns of device performance by ultrasound device subgroups:

Table 5.7.2: Performance Analysis of device on thyroid lobe volume measurement for Ultrasound Device Subgroups

	Thyroid Lobe Volume (cc)			
Subgroup	**AI**	**Ref. data**	**ICC**	**Maximum % Volume Error**
Siemens	4.27 ± 2.61	4.35 ± 2.66	0.974 (95% CI 0.967–0.978)	18.2% (95% CI 12.0-24.0)
Philips	6.12 ± 3.73	5.95 ± 3.57	0.963 (95% CI 0.952-0.969)	21.1% (95% CI 16.5-25.0)
GE	8.08 ±10.02	7.73 ± 9.99	0.974 (95% CI 0.969-0.977)	24.4% (95% CI 20.0-29.5)
All	6.48 ± 6.54	6.29 ± 6.46	0.972 (95% CI 0.969-0.975)	21.7% (95% CI 19.0-24.8)

Table 5.7.3: Performance Analysis of device on nodule volume measurement for Ultrasound Device Subgroups

	Thyroid Nodule Volume (cc)			
Subgroup	**AI**	**Ref. data**	**ICC**	**Maximum % Volume Error**
Siemens	0.85 ± 1.19	0.87 ± 1.22	0.978 (95% CI 0.975–0.979)	17.4% (95% CI 12.0-24.0)
Philips	1.76 ± 2.95	1.76 ± 3.07	0.972 (95% CI 0.967-0.975)	23.5% (95% CI 16.5-25.0)
GE	1.83 ± 5.71	1.93 ± 6.34	0.974 (95% CI 0.969-0.977)	24.6% (95% CI 20.0-29.5)
All	1.61 ± 3.71	1.64 ± 4.02	0.973 (95% CI 0.971-0.975)	22.9% (95% CI 20.0-26.0)

The performance of the MEDO-Thyroid device has been successfully assessed on a nodule size range between 0.13 cc and 36.5 cc, and is independent of the sizes of nodules being measured.

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-Thyroid raises no new questions of safety or effectiveness and is substantially equivalent to the predicate device in terms of safety, efficacy, and performance.