Nesa Medtech Private Limited
% Rob Packard
President/Consultant
Medical Device Academy, Inc.
345 Lincoln Hill Road
SHREWSBURY VT 05738

July 17, 2023

Re: K222683
Trade/Device Name: Fibroid Mapping Reviewer Application (FMRA)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: September 6, 2022
Received: June 9, 2023

Dear Rob Packard:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Imaging Devices
and Electronic Products
OHT8: Office of 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)*
K222683

Device Name
Fibroid Mapping Reviewer Application (FMRA)

Indications for Use *(Describe)*
Fibroid Mapping Reviewer Application (FMRA) is intended to be used by physicians in the clinic or hospital to generate a 3-D model from ultrasound images of the uterus of women with uterine fibroids. The model represents clinically relevant dimensions, including the location and dimensions of the fibroid (maximum length, width and depth).

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 submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

Nesa Medtech Private Limited
15, 33rd Main 7th Block Bhavani Colony, Banashankari 3rd Stage,
Banashankari, Bengaluru, Karnataka 560085, India

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Date Prepared: October 25, 2022

II. DEVICE

Name of Device:	Fibroid Mapping Reviewer Application (FMRA)
Classification Name:	Medical Image Management and Processing System
Regulation:	21 CFR §892.2050
Regulatory Class:	Class II
Product Classification Code:	LLZ

III. PREDICATE DEVICE

Predicate Manufacturer:	Eigen LLC
Predicate Trade Name:	3-D Imaging Workstation
Predicate 510(k):	K081093

IV. DEVICE DESCRIPTION

Fibroid Mapping Reviewer Application (FMRA) is a software that allows the user to load an existing ultrasound data into the application for calibration, review, annotation and generation of a 3D rendered uterus model. It aids in the measurement of fibroid dimensions and mapping the location of fibroids in the uterus.

The ultrasound data of the patient's uterus, exported from ultrasound equipment via storage media such as a USB drive, is loaded into the proposed software. The user marks the anatomical features of the uterus and the fibroid. The software post-processes the 2D volume ultrasound images of the uterus to obtain the mapping & measurement of fibroids which are represented in a 3D rendered uterus model. It allows the clinician to know the parameters of each fibroid (like fibroid size and location) by just selecting a fibroid in the model.

The proposed device is intended to assist qualified physicians in accurate diagnosis and planning of image guided interventional of uterine fibroids.

V. INDICATIONS FOR USE

Fibroid Mapping Reviewer Application (FMRA) is intended to be used by physicians in the clinic or hospital to generate a 3-D model from ultrasound images of the uterus of women with uterine fibroids. The model represents clinically relevant dimensions, including the location and dimensions of the fibroid (maximum length, width and depth).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

Feature	Subject Device	Predicate Device	Comparison
Name	Fibroid Mapping Reviewer Application (FMRA)	3-D Imaging Workstation	N/A
510(k)	-	K081093	N/A
Indications for Use	Fibroid Mapping Reviewer Application (FMRA) is intended to be used by physicians in the clinic or hospital to generate a 3-D model from ultrasound images of the uterus of women with uterine fibroids. The model represents clinically relevant dimensions, including the location and dimensions of the fibroid (maximum length, width and depth).	The 3-D Imaging Workstation is intended to be used by physicians in the clinic or hospital for 2-D and 3-D visualization of ultrasound images of the prostate gland. Additional software features include patient data management, multi-planar reconstruction, segmentation, image measurement and 3-D image registration.	The subject devices are indicated for different targeted anatomies. The intended use of visualizing ultrasound images is the same.
Product Code	LLZ	LLZ	Same
Class	II	II	Same
Windows OS	Windows OS (10)	Windows OS	Same
Medical imaging software	Yes	Yes	Same
General Image 2DReview	2D ultrasound frames can be reviewed	2D ultrasound frames can be reviewed	Same
3D Rendering View	2D ultrasound data is converted into 3D rendered model	2D ultrasound data is converted into 3D rendered model	Same

Import/Export	Exported from commercially available ultrasound machines via storage media such as a USB drive	Live video received from commercially available ultrasound machines	Different. The difference in the method of import/export of data does not raise questions of safety and effectiveness.
Review Tools	Yes	Yes	Same
Measurement Tools	Yes	Yes	Same
Annotation Tools	Yes	Yes	Same
Patient data management	Yes	Yes	Same
Image Storage and Communication	.mov, .avi, .mp4	DICOM, jpeg	Different. The difference in the format of data does not raise questions of safety and effectiveness.

VII. PERFORMANCE DATA

The overall verification & validation activities performed for FMRA includes the following:

- Product & Engineering specifications were verified & validated.
- Validation of FMRA included a comparison of the accuracy of FMRA output parameters on phantom models (i.e., incorporating simulated uterus and fibroids) with MRI values.
    - MRI Imaging is considered to be the gold standard for imaging.
    - Acceptance criteria between FMRA Output parameters & MRI Values -
        - Location – Variation of spatial co-ordinate should be within +/- 2 MM
        - Dimensions – Variation of fibroid dimensions should be within +/- 2 MM
    - Validation testing was executed by 3 certified medical professionals, and the input images for FMRA were also collected from 3 different ultrasound machines.

The following standards were followed in the development of the FMRA:

- ISO 14971: 2019 Medical Devices - Application of Risk Management to Medical Devices
- IEC 62304: 2015 Medical Device Software - Software Life Cycle Processes

FMRA passed all applicable testing in accordance with acceptance criteria and also relevant standards. The results demonstrate that the FMRA satisfies the performance, functional, and safety requirements relative to the product specifications, risk analyses, and Instructions for Use, and does not raise different questions of safety and effectiveness than the predicate device.

VIII. CONCLUSIONS

The Fibroid Mapping Reviewer Application i.e. FMRA has the same intended use as the predicate devices. Intended use of both the systems are to process the targeted features/ anatomies in 2-D ultrasound images deriving 3D representative models. The subject device is using this technology to visualize and measure fibroid dimension and location relative to other anatomy. The predicate device uses this technology to visualize the prostate gland. For both, ultrasound is the traditional method for evaluating the respective indicated uses, and both the subject device and predicate devices are software applications that improve the provider's ability to use the ultrasound information. Performance tests demonstrate that the FMRA has been tested to prove the same. The biological sex of the patient does not impact the performance of the ultrasound relating to its ability to capture images of targeted tissues and therefore does not impact the equivalence of the technology's performance in the respective sex. The method of acquisition (transvaginal vs, transrectal) is also not a substantial difference because the method and means of acquiring the image is not important, but what is important for each system is that the ultrasound views captured are within the required specifications for each software. This relates more to the specific indications as opposed to the general intended use