July 14, 2025

Narnar, LLC
℅ Meri Martinez
Regulatory Affairs Project Manager
Innoltics, LLC
1101 West 34th St. #550
Austin, Texas 78705

Re: K250120
Trade/Device Name: GECHO
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: June 27, 2025
Received: June 27, 2025

Dear Meri Martinez:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Jessica Lamb, PhD.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250120

Device Name

GECHO

Indications for Use *(Describe)*

GECHO is a software package intended to visually assess contrast-enhanced echocardiography for left ventricular function and myocardial blood flow by displaying enhanced images of the heart and Time-To-Replenish images. GECHO is intended for use by a cardiologist.

GECHO is for use on images of adult patients who underwent contrast-enhanced echocardiography.

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."

1. Contact Information

Company Name	narnar, LLC
Address	525 3rd St, Suite 231 Lake Oswego, OR 97034
Phone Number	503-442-9273
Company Representative	Jiri Sklenar, CEO
Email	jiri@narnarhealth.com
Primary Correspondent	Jiri Sklenar, CEO
Primary Correspondent Email	jiri@narnarhealth.com
Date Summary Prepared	January 16th, 2025

2. Device Information

Trade Name	GECHO
Common Name	Radiological Image Processing System
Product Code	LLZ
Regulation Number	892.2050
Class	Class II
Panel	Radiology

3. Predicate Device Information

Predicate Device Name	QLAB Advanced Quantification Software
Predicate Device K Number	K181264
Product Code	LLZ
Regulation Number	892.2050
Class	Class II
Panel	Radiology

4. DEVICE DESCRIPTION

GECHO is an image review platform and analysis software that assists cardiologists in the interpretation of left ventricular function and myocardial blood replenishment from two-dimensional, contrast-enhanced echocardiograms.

5. INTENDED USE/INDICATIONS FOR USE

GECHO is a software package intended to visually assess contrast-enhanced echocardiography for left ventricular function and myocardial blood flow by displaying enhanced images of the heart and Time-To-Replenish images. GECHO is intended for use by a cardiologist.

GECHO is for use on images of adult patients who underwent contrast-enhanced echocardiography.

5.1. Contraindications for Use

GECHO is not for use for pediatric patients. GECHO is not for use on organs other than the heart.

6. SUBSTANTIAL EQUIVALENCE DISCUSSION

Table 1. Comparison of the Intended Use and Technological Characteristics of GECHO and the Predicate Device.

Row #	Characteristic	Subject Device	Predicate Device	Differences
1	Trade Name	GECHO	QLAB Advanced Quantification Software	N/A
2	Manufacturer	narnar, LLC	Philips Ultrasound Inc.	N/A
3	K#	K250120	K181264	N/A
4	Device classification	Class II	Class II	None.
5	Indications for Use / Intended Use Statement	GECHO is a software package intended to visually assess contrast-enhanced echocardiography for left ventricular function and myocardial blood flow by displaying enhanced images of the heart and Time-To-Replenish images. GECHO is intended for	QLAB Advanced Quantification Software is a software application package. It is designed to view and quantify image data acquired on Philips ultrasound systems.	Both devices have similar indications for use. The main difference is that the predicate is indicated for use on Philips ultrasound systems, while the subject device is compatible with multiple manufacturers.

Row #	Characteristic	Subject Device	Predicate Device	Differences
		use by a cardiologist. GECHO is for use on images of adult patients who underwent contrast-enhanced echocardiography.		
6	Device Type	Radiological Image Processing System	Radiological Image Processing System	None.
7	Classification Regulation	21 C.F.R. § 892.2050	21 C.F.R. § 892.2050	None.
8	Product Code	LLZ	LLZ	None.
9	510(k) Exempt	No	No	None.
10	Rx/OTC	Rx only	Rx only	None.
11	Patient Population	Anyone eligible for contrast-enhanced echocardiography.	Unspecified.	None. Neither the subject nor predicate device is indicated for use by a limited patient population.
12	Intended Use Environments	Echocardiography reading rooms.	Clinics, hospitals, office-based practices, and clinical point-of-care settings.	The intended use environment of GECHO is within the scope of those of the predicate device, therefore this difference does not raise additional questions of safety or effectiveness.
13	Module of Interest	N/A	Cardiac Parametric Quantification (Cardiac PQ) Q-App.	GECHO has specialized functionality that is comparable to the function of the QLAB Cardiac PQ Q-App. Q-App modules of the predicate device function independently, so this does not raise questions of safety or effectiveness.
14	Anatomical Region	Heart	Heart	None.
15	Scan Type	Echocardiogram	Echocardiogram	None.
16	Software only device?	Yes	Yes	None.

Row #	Characteristic	Subject Device	Predicate Device	Differences
-	**Key Functions and Features**	-	-	-
17	Manual, editable segmentation of the myocardium	Yes	Yes	None.
18	Automated image stabilization	Yes	Yes	None.
19	Automatic detection of the first frame after flash images with optional manual overwrite	Yes	Yes	None.
20	Automatic ECG gating with optional manual overwrite	Yes	Yes	None.
21	Image averaging of stabilized, ECG-gated images	Yes	No	Image averaging is a common noise-reduction technique that does not represent a clinically meaningful risk to the safety or effectiveness of GECHO.
22	Baseline subtraction and color coding	Yes	No	Digital subtraction is an established technique in contrast radiology that does not represent a significant risk to the safety or effectiveness of GECHO.
23	Parametric Imaging using (1-exp) function	Yes	Yes	None.
24	Use of color palettes to display parametric images.	Yes	Yes	None.
-	**Technical Specifications**	-	-	-

Row #	Characteristic	Subject Device	Predicate Device	Differences
25	Input file type	DICOM file – R-wave tagged image sequences captured during an exam using a contrast agent. Power mode data is not supported.	DICOM files – R-wave tagged image sequences captured during an exam using a contrast agent. Including echo or power mode data. Minimum of 4 R-waves in each scan.	The input files accepted by GECHO are a subset of files supported by QLAB.
26	Output file type	DICOM Secondary capture, DICOM SR	DICOM Secondary capture, DICOM SR, AVI files	GECHO outputs are a subset of files outputted by QLAB.
-	**Required Testing**	-	-	-
27	Clinical testing required?	No	No	None.
28	Software verification & validation required?	Yes	Yes	None.

7. PERFORMANCE DATA

7.1. Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by 2023 FDA Guidance "Content of Premarket Submissions for Device Software Functions".

The software verification and validation testing verified that the design requirements were successfully met. The Intended use and user needs were successfully validated.

As the intended use, functionality and performance of the subject device and the predicate device are equivalent, the result of the performance testing is evidence that the GECHO performs in an equivalent manner to the QLAB Advanced Quantification Software.

7.2. Technical Performance Assessment

Technical performance assessment of the subject device involved evaluating the Time-to-Replenish Output (TTR) as recommended by 2022 FDA Guidance "Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions".

The TTR algorithm was tested on synthetic data across a wide range of representative clinical data parameters. Tested parameters included TTR, plateau videointensity (A), the number of selected frames (or heart cycles), heart rate and normalized mean square error (NMSE).

Additionally, an expert survey was conducted to ensure the TTR image correctly represents the information present in raw images and is intuitive and useful, in combination with raw images, for the interpretation of myocardial blood flow.

The TTR (Time-to-Replenish) algorithm demonstrated strong performance with these key metrics:

- RMSE of 0.98 seconds, showing high accuracy
- Minimal bias of 0.0025 seconds
- Can detect TTR values down to 0.5 seconds
- Performs well even with noise (NMSE up to 0.05)

These results validate that the algorithm is reliable for assessing myocardial blood flow in clinical settings.

7.3. Clinical Performance Testing

No clinical performance data was necessary to claim substantial equivalence.

8. CONCLUSION

The GECHO shares similar technological characteristics, intended use, and functionality with the predicate device. There are no differences between the devices that raise new questions of safety and effectiveness.

Furthermore, technical performance test data and software verification and validation demonstrate that GECHO performs comparably to the predicate device in terms of safety and effectiveness.

Based on the device comparisons and the acceptable testing results, it is determined that GECHO is substantially equivalent to the predicate device.