ThinkSono GmbH
Dignesh Shah
Regulatory Lead
C/O Hpi Seed Fund Gmbh, August-Bebel-Straße 88
Potsdam, 14482
Germany

July 15, 2026

Re: K260338
Trade/Device Name: ThinkSono Guidance
Regulation Number: 21 CFR 892.2100
Regulation Name: Radiological Acquisition And/Or Optimization Guidance System
Regulatory Class: Class II
Product Code: QJU
Dated: June 15, 2026
Received: June 15, 2026

Dear Dignesh Shah:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Digitally signed by Michael D. O'hara -S
Date: 2026.07.15 13:57:35 -04'00'

For

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260338

Please provide the device trade name(s).

ThinkSono Guidance

Please provide your Indications for Use below.

The ThinkSono Guidance software is intended to assist non-ultrasound-trained healthcare professionals in the acquisition of vascular ultrasound images by providing real-time guidance during probe positioning and image acquisition.

The software is compatible with point-of-care diagnostic ultrasound systems. ThinkSono Guidance does not assist in interpretation of ultrasound images.

ThinkSono Guidance is indicated for adult patients who require a lower extremity compression ultrasound exam for the evaluation of suspected deep vein thrombosis (DVT).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K260338

510(k) SUMMARY

ThinkSono Guidance

This summary is provided in accordance with the requirements of 21 CFR 807.92.

Contact Details

Applicant Name	ThinkSono GmbH
Applicant Address	c/o HPI Seed Fund GmbH, August-Bebel-Straße 88, 14482 Potsdam, Germany
Contact Person	Dr. Dignesh G. Shah, Regulatory Lead
Contact Email	hello@thinksono.com
Contact Telephone	+44 7889 565310
Date Prepared	13 July 2026

Device Identification

Device Trade Name	ThinkSono Guidance
Classification Name	Image Acquisition And/Or Optimization Guided By Artificial Intelligence
Regulation Number	21 CFR 892.2100
Product Code	QJU
Device Class	II
Review Panel	Radiology

Predicate Device

Legally Marketed Predicate Device	Caption Guidance (Caption Health, Inc.), DEN190040

Intended Use and Indications for Use

Indications for Use

The ThinkSono Guidance software is intended to assist non-ultrasound-trained healthcare professionals in the acquisition of vascular ultrasound images by providing real-time guidance during probe positioning and image acquisition. The software is compatible with point-of-care diagnostic ultrasound systems.

ThinkSono Guidance does not assist in interpretation of ultrasound images. ThinkSono Guidance is indicated for adult patients who require a lower extremity compression ultrasound exam for the evaluation of suspected deep vein thrombosis (DVT).

Device Description

ThinkSono Guidance is a radiological acquisition and/or optimization guidance system that provides real-time guidance to a non-ultrasound-trained operator to perform a standardized compression ultrasound examination and obtain cine-loop videos for the evaluation of lower extremity deep vein thrombosis (DVT).

The system comprises the ThinkSono Guidance Mobile App and the ThinkSono Guidance Dashboard. The Mobile App interfaces with a compatible ultrasound scanner, analyzes its B-mode images, and guides the operator in recording venous compression cine-loops. A remote qualified clinician uses the Dashboard to evaluate the cine-loops for DVT. As a data-collection tool, ThinkSono Guidance does not generate a diagnostic interpretation; all clinical decisions remain under the authority of the qualified clinician.

The device provides the following core functionality:

- **Real-time image acquisition guidance:** the Mobile App highlights vascular structures and provides real-time feedback on scanner placement so that anatomical sites relevant to lower extremity DVT are consistently imaged during cine-loop recording.
- **Structured capture with predicted compression quality:** the app prompts the operator to record when a suitable view is found and screens each clip for common scanning pitfalls, prompting a re-record where quality is insufficient. The operator can retry or cancel at any point.
- **Evaluation by qualified clinicians:** cine-loops are transmitted to a remote qualified clinician who first grades image quality on the ACEP 1–5 scale and, where quality is adequate (ACEP ≥ 3), assesses vein compressibility (compressible / incompressible / indeterminate). Inadequate studies can be routed back to the operator for targeted re-acquisition.

ThinkSono Guidance operates with compatible, FDA-cleared general-purpose handheld point-of-care ultrasound scanners, including the Clarius scanner families cleared under K192107 (Clarius HD), K213436 (Clarius HD3), and K232704 (Clarius PAL HD3).

Technological Characteristics

Both the predicate device and ThinkSono Guidance facilitate AI-guided acquisition of ultrasound cine-loops. ThinkSono Guidance has the same intended use and substantially equivalent indications for use as the predicate device.

The ThinkSono Guidance software is similar in its technological features to its predicate device. Both systems are intended as an assistive tool to aid medical professionals in the acquisition of ultrasound images. While the predicate device is intended for cardiac imaging, ThinkSono Guidance is indicated for vascular imaging related to deep vein thrombosis in the lower extremity.

The technological characteristics of ThinkSono Guidance are substantially equivalent to the technological characteristics of the predicate device. Both systems apply machine-learning based algorithms to provide real-time guidance on how to position and manipulate the ultrasound scanner on a patient's body. Both systems are coupled with a third-party, previously cleared ultrasound system and provide to the users real-time guidance during acquisition of ultrasound images to assist them in obtaining diagnostic quality images.

These differences do not raise new questions of safety or effectiveness.

Substantial equivalence is demonstrated in the table below that compares the features (similarities and differences) of the subject and the predicate device.

Table 1: Substantial Equivalence Comparison

Parameter	Caption Guidance (DEN190040)	ThinkSono Guidance (K260338)	Conclusion
Classification name	Image Acquisition And/Or Optimization Guided By Artificial Intelligence	Same	Identical

Parameter	Caption Guidance (DEN190040)	ThinkSono Guidance (K260338)	Conclusion
Product code / Regulation	QJU / 892.2100	Same	Identical
Device class	II	II	Identical
Intended use	The Caption Guidance software is intended to assist medical professionals in the acquisition of cardiac ultrasound images. Caption Guidance software is an accessory to compatible general purpose diagnostic ultrasound systems.	The ThinkSono Guidance software is intended to assist non-ultrasound-trained healthcare professionals in the acquisition of vascular ultrasound images by providing real-time guidance during probe positioning and image acquisition. The software is compatible with point-of-care diagnostic ultrasound systems. ThinkSono Guidance does not assist in interpretation of ultrasound images.	Same. Both have the same image acquisition function: assisting non-specialist medical professional operators in acquiring diagnostic-quality ultrasound images.
Indications for use	The Caption Guidance software is indicated for use in two-dimensional transthoracic echocardiography (2D-TTE) for adult patients, specifically in the acquisition of the following standard views: Parasternal Long-Axis (PLAX), Parasternal Short-Axis at the Aortic Valve (PSAXAV), Parasternal Short-Axis at the Mitral Valve (PSAX-MV), Parasternal Short-Axis at the Papillary Muscle (PSAX-PM), Apical 4-Chamber (AP4), Apical 5-Chamber (AP5), Apical 2-Chamber (AP2), Apical 3-Chamber (AP3), Subcostal 4-Chamber (SubC4), and Subcostal Inferior Vena Cava (SCIVC).	ThinkSono Guidance is indicated for adult patients who require a lower extremity compression ultrasound exam for the evaluation of suspected deep vein thrombosis (DVT).	Substantially equivalent. Although the predicate device is for cardiac scanning while the subject device is for lower extremity compression ultrasound.
Intended Patient Population	Patients who can undergo two- Dimensional transthoracic echocardiography (2D-TTE).	Patients suspected of deep vein thrombosis (DVT)	Different. Addressed by clinical and non-clinical performance testing; does not raise new

Parameter	Caption Guidance (DEN190040)	ThinkSono Guidance (K260338)	Conclusion
			questions of safety or effectiveness.
Body part / condition	Cardiac region/2D-TTE can confirm clinical diagnosis of aortic stenosis and provide specific data on LV function.	Legs of suspected DVT patients.	Different. Addressed by clinical and non-clinical performance testing; does not raise new questions of safety or effectiveness.
Intended Users	Device users: Physicians (Hospitalists) Nurse Practitioners and Physician Assistants Registered Nurses (RNs) Medical Residents Certified Medical Assistants Trained Sonographers Ultrasound images: Cardiologists	Operator User Group: Non-ultrasound-trained healthcare professionals working at the point of care. These users include: Physicians (attending and resident) Nurse Practitioners (NPs) and Physician Assistants (PAs) Registered Nurses Certified Medical Assistant (CMA) Reviewer User Group: Qualified Clinicians	Substantially equivalent. Same image acquisition users i.e non-ultrasound specialist medical professionals. The predicate device can also be operated by trained sonographers. Same image interpretation and decision- making users – qualified medical professionals (qualified clinicians for Subject Device, cardiologists for Predicate Device).
Compatible ultrasound system	The uSmart 3200t Plus ultrasound system with the 3200t-compatible Terason 4V2A linear phased array probe.	Cleared Clarius handheld scanners (K192107, K213436, K232704).	Substantially equivalent. Both operate on cleared, general-purpose ultrasound hardware.
Machine-learning based algorithm	Yes	Yes	Substantially equivalent.
Image acquisition guidance	The Caption Guidance software is a radiological acquisition and/or optimization guidance system that provides real-time guidance to the users during acquisition of echocardiography to assist them in obtaining anatomically correct images that represent standard 2D echocardiographic	The ThinkSono Guidance software is a radiological acquisition and/or optimization guidance system that provides real-time guidance to a non-ultrasound-trained operator to perform a standardized compression ultrasound examination and obtain cine-loop videos.	Substantially equivalent. While the user interface is different, the functionality and type of guidance provided to the user will be the same. Specifically, both devices provide users with instructions on how to maneuver the probe with real-time feedback during acquisition of ultrasound

Parameter	Caption Guidance (DEN190040)	ThinkSono Guidance (K260338)	Conclusion
	diagnostic views and orientations. Caption Guidance is a software-only device that uses artificial intelligence to emulate the expertise of sonographers.	The ThinkSono Guidance is software that uses an artificial intelligence (AI) algorithm to ensure that the anatomical sites defined by the American College of Emergency Physicians (ACEP) are consistently imaged. As a data collection tool, ThinkSono Guidance does not generate a diagnostic interpretation. All clinical decisions remain under the authority of the qualified clinician.	images. They direct the user to a probe position that will enable acquisition of a diagnostic quality cine loop. Hence, this difference in user interface does not raise new questions of safety and/or effectiveness.
Real-time image-quality feedback	Quality Meter: real-time feedback from the Quality Meter advises the user on the expected diagnostic quality of the resulting clip, such that the user can make decisions to further optimize the quality, for example by following the prescriptive guidance feature	The software provides real-time feedback on scanner placement and cine-loop acquisition via an AI algorithm, ensuring that the anatomical sites defined by the American College of Emergency Physicians (ACEP) are consistently imaged. The AI guidance is only provided in real-time as the operator records the cine-loop.	Substantially equivalent.
Automatic Capture of Clips and Predicted Diagnostic Quality **Save Best Clip**	Auto-Capture: The Caption Guidance Auto-Capture feature triggers an automatic capture of a clip when the quality is predicted to be diagnostic, emulating the way in which a sonographer knows when an image is of sufficient quality to be diagnostic and records it. Save Best Clip: This feature continually assesses clip quality while the user is scanning and, in the event that the user is not able to obtain a clip sufficient for Auto-Capture, the software	Structured Capture of Cine Loops and Predicted Compression Quality: In the user interface of the ThinkSono Guidance Mobile App, the operator is instructed to record a cine-loop when a correct view is found. The app analyzes the clip for common scanning pitfalls, such as moving the veins out of the field of view and suggests to the operator to re-record the cine-loop. The operator can also retry or cancel the cine-loop recording at any point.	Substantially equivalent. The differences in user interface and functioning of the subject and predicate device do not raise new questions of safety and/or effectiveness.

Parameter	Caption Guidance (DEN190040)	ThinkSono Guidance (K260338)	Conclusion
	allows the user to retrospectively record the highest quality clip obtained so far, mimicking the choice a sonographer might make when recording an exam.	All cine loops are then reviewed by a qualified clinician for final clinical decision making.	

Substantial Equivalence

ThinkSono Guidance is as safe and effective as the predicate device. The ThinkSono Guidance software has the same intended uses and similar indications for use and technological characteristics, and principles of operation as its predicate device. The technological differences between ThinkSono Guidance and its predicate device raise no new questions of safety and effectiveness.

Performance data demonstrate that ThinkSono Guidance is as safe and effective as Caption Guidance. Therefore, ThinkSono Guidance is substantially equivalent to the predicate device.

Performance Data

ThinkSono has considered the requirements of special controls of the predicate device and ensured compliance with performance testing of the ThinkSono Guidance via non-clinical testing, clinical testing and labeling. Compliance with the special controls addressed all questions of safety and/or effectiveness proving substantial equivalence to the predicate device.

Usability and Human Factors Validation

A summative usability study was conducted with 15 participants per user group under simulated and clinical conditions, following use-related risk analysis to identify critical tasks. All participants completed 100% of critical tasks, user satisfaction was 96% favorable across usability aspects, and no critical use errors or patient risks occurred.

Algorithm Performance (Bench)

The algorithm was trained and validated on 281,534 annotated ultrasound images from 520 exams (3,182 cine-loops, 222 showing pathology). Performance was assessed on a separate, prospectively acquired test set of 22,124 annotated images from 197 cine-loops across 43 patients scanned by nurses using ThinkSono Guidance. Algorithm outputs (vessel/landmark segmentation masks and landmark classifications) are used to guide acquisition and to flag clips for re-recording; they do not produce a diagnostic result.

On a 216-video compression-quality evaluation set, the algorithm met its pre-specified acceptance criteria:

Metric	Result
Sensitivity	96% (70/73)
Specificity	96% (74/77)
Retry accuracy	86% (186/216)

These bench metrics characterize per-cine-loop guidance behavior in a controlled simulation and do not represent patient-level diagnostic performance; the compressibility output is not surfaced in the Mobile App during intended use, and each examination includes multiple compressions for redundancy.

Clinical Performance Data

ThinkSono conducted a series of prospective, double-blinded, multicenter investigations of ThinkSono Guidance as a data-collection tool with qualified-clinician review in adult patients with suspected lower extremity proximal DVT. Each patient underwent a reference-standard specialist duplex scan and a ThinkSono Guidance scan performed by a non-ultrasound-trained operator (60–90 minutes of standardized training). Cine-loops were independently interpreted by blinded, U.S.-credentialed remote qualified clinicians for ACEP image quality and vein compressibility.

The pivotal U.S. study enrolled 594 patients across 5 sites with 67 confirmed DVTs. Across all U.S. and OUS studies, 24 sites and 1,691 patients were recruited (157 confirmed DVTs). Median operator scan time was 5:24 minutes and median review time was 2:13 minutes.

Study subjects were adults clinically indicated for lower extremity venous ultrasound, recruited across the five U.S. sites with a representative range of age, sex, BMI, and race/ethnicity, and located in diverse geographic regions of the United States. Age and BMI distributions were comparable between the U.S. and OUS cohorts, and device performance was consistent across them. Operators reflected the real-world intended user base (physicians, nurse practitioners, physician assistants, registered nurses, and certified medical assistants), and the remote qualified clinician reviewers spanned emergency medicine, vascular surgery, and radiology.

A bivariate meta-analysis across U.S. and OUS data demonstrated:

- Adequate diagnostic image quality: 87.1% (95% CI 78.2–92.7)
- Pooled sensitivity: 92.9% (95% CI 86.3–96.4)
- Triage specificity: 57.8% (95% CI 34.5–78.1)
- Prioritization specificity: 97.1% (95% CI 94.6–98.5)

The diverse subject population, operators, and reviewers reflect anticipated real-world use, supporting the external validity and generalizability of these results to the U.S. population. The findings demonstrate that ThinkSono Guidance enables safe and efficient DVT assessment where immediate access to imaging specialists may be limited.

Subgroup analyses

135 U.S. patients, ≥10 per subgroup showed stable algorithm segmentation (Dice) and landmark (F1) performance across race/ethnicity, age, sex, and BMI, with no subgroup showing systematic degradation. This is consistent with the clinical subgroup analysis (n=594), in which adequate image quality ranged from 82.5% to 95.9% and triage sensitivity from 89.4% to 100% across demographic subgroups.

Conclusions

The nonclinical and clinical testing summarized above demonstrates that ThinkSono Guidance is as safe as, as effective as, and performs as well as the legally marketed predicate device.

ThinkSono Guidance has the same intended use and the same principles of operation as the predicate device. Its indications for use differ in the anatomy examined and the associated clinical condition; for the reasons set out above, those differences are not critical to the intended diagnostic use of the device and do not affect its safety and effectiveness when used as labeled.

The differences in technological characteristics raise no new questions of safety or effectiveness and are supported by algorithm performance testing, software verification and validation, human factors validation, and prospective multicenter clinical investigation in the intended U.S. patient population.

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified.