September 30, 2025

Astrasono Technology Co., Ltd
℅ Charles Shen
Director
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K250331
Trade/Device Name: Astrasono A3Pro Bladder Scanner (A3Pro)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: August 29, 2025
Received: August 29, 2025

Dear Charles Shen:

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,

YANNA S. KANG -S

Yanna Kang, Ph.D.
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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)*

K250331

Device Name

Astrasono A3Pro Bladder Scanner (A3Pro)

Indications for Use *(Describe)*

The “Astrasono A3Pro Bladder Scanner” is B-mode pulsed-echo ultrasound device. It is intended as a handheld battery-operated device. The device projects ultrasound energy through the lower abdomen of the patient to obtain images of the bladder which is used to calculate bladder volume noninvasively. It is intended to be used only by qualified medical professionals.

Environments of intended use：Professional medical environments
The intended patient population: Adult patients who require bladder volume measurement (not applicable to pediatric patients).

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: K250331

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92

1.0 Submitter Information

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Date of Summary: January 31, 2025

2.0 Device Information

Proprietary Name:	Astrasono A3Pro Bladder Scanner (A3Pro)
Common Name:	Bladder Scanner
Classification Name:	System, Imaging, Pulsed Echo, Ultrasonic
Device Classification:	II
Regulation Number:	21 CFR 892.1560
Product Code:	IYO, ITX
Panel:	Radiology

3.0 Predicate Device Information:

Manufacturer:	SUZHOU PEAKSONIC MEDICAL TECHNOLOGY CO., LTD.
Product Name:	Bladder Scanner, Model M3, M3-HD, M4, M4-HD
510(K) #:	K201316

4.0 Device description:

The "Astrasono A3Pro Bladder Scanner" is a hand-held battery-operated device, it provides non-invasive bladder volume measurement utilizing real-time ultrasound imaging.

The "Astrasono A3Pro Bladder Scanner" measures the bladder volume in the range of 0 – 999 mL.

There are three scanning modes (all B-modes): Easy Mode, Expert Mode, and Empower Mode:

- Easy Mode: Under this mode, the screen displays a real-time image of bladder silhouette.
- Expert Mode: Under this mode, the screen displays a real-time image of bladder.
- Empower Mode: Under this mode, the screen displays a real-time image of bladder projection.

This device consists of a console (including a rechargeable Li-ion battery pack and built-in printer), a probe, and a medical switching power supply.

The obtained ultrasound images and calculated bladder volume results can be downloaded to USB drive as encrypted Data.

5.0 Indications for Use:

The "Astrasono A3Pro Bladder Scanner" is B-mode pulsed-echo ultrasound device. It is intended as a handheld battery-operated device. The device projects ultrasound energy through the lower abdomen of the patient to obtain images of the bladder which is used to calculate bladder volume noninvasively. It is intended to be used only by qualified medical professionals.

Environments of intended use: Professional medical environments
The intended patient population: Adult patients who require bladder volume measurement (not applicable to pediatric patients)

6.0 Comparison to Predicate Devices

The "Astrasono A3Pro Bladder Scanner" manufactured by *"Astrasono Technology Co., Ltd"* is compared with the following Predicate Device in terms of intended use, design, material, specifications, and performance.

(1) K201316, "Bladder Scanner, Model M3, M3-HD, M4, M4-HD", manufactured by "SUZHOU PEAKSONIC MEDICAL TECHNOLOGY CO., LTD."

The following table shows similarities and differences of use, design, and material between our devices and the predicate device.

Table 5.1: Comparison of Intended Use, Design, and Material

SE Comparisons	Subject Device	Predicate Device (K201316)	Comments
Trade Name and Model	Astrasono A3Pro Bladder Scanner	Bladder Scanner (Models: M3, M3-HD, M4, M4-HD)	/
Product Code	IYO, ITX	IYO, ITX	Same
Indication for use	The "Astrasono A3Pro Bladder Scanner" is B-mode pulsed-echo ultrasound device. It is intended as a handheld battery-operated device. The device projects ultrasound energy through the lower abdomen of the patient to obtain images of the bladder which is used to calculate bladder volume noninvasively. It is intended to be used only by qualified medical professionals. Environments of intended use: Professional medical environments The intended patient population: Adult patients who require bladder volume measurement (not applicable to pediatric patients)	The Bladder Scanner (Models: M3, M3-HD, M4, M4-HD) projects ultrasound energy through the lower abdomen of the patient to obtain images of the bladder which is used to calculate bladder volume noninvasively. The Bladder Scanner is intended to be used only by qualified medical professionals.	Same

Contraindications	Do not use the Bladder Scanner on following cases: 1) Fetal use or pregnant patients 2) Patients with ascites 3) Patients with open or damaged skin 4) Wounds in the suprapubic region	Do not use the Bladder Scanner on following cases: 1) Fetal use or pregnant patients 2) Patients with ascites 3) Patients with open or damaged skin 4) Wounds in the suprapubic region	Same
Modes of Operation	B mode	B mode	Same
Track	Track 3	Track 1	Different
Display	TFT-LCD and Thermal Printer	Smart Phone and Thermal Printer	Different
Power Source	Li Battery	Li Battery	Same .
Controls of Acoustic Output	No	No	Same
Transducer Type	Mechanical Sector Probe	Mechanical Sector Probe	Same
Anatomic Position	Abdomen	Abdomen	Same
Patient Contact	Intact Skin	Intact Skin	Same
Transducer Frequency	2.5Mhz	2.5Mhz	Same
Number of Elements	1	1	Same
Sector Angle	120°	120°	Same
Number of Scan Planes	12	M4, M4-HD:12	Same
Measurement Range	0 ml – 999 ml	0 ml - 999 ml	Same
Real-time Scanning	Yes (Pre-scan)	Yes (Pre-scan)	Same
Data Download	USB connection	USB connection	Same
WIFI	No	WIFI connection.	Different
Bluetooth	Disabled	Enabled	Different

The Indications for Use, working mechanisms, design and technological characteristics of the subject device is similar to the predicate device. The minor differences between the subject device and predicate device do not raise any concerns in terms of safety and effectiveness.

7.0 Non-Clinical Study Summary

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

1) *IEC 60601-1: 2005/AMD1: 2012/AMD2: 2020, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
2) *IEC 60601-1-2: 2014, Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances –Requirements and tests*
3) *IEC TS 60601-4-2:2024: Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems*
4) *IEC 60601-2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment*
5) *IEC 62359: 2010+AMD1 2017, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields*
6) *NEMA UD 2 Standard for real-time display of thermal and mechanical acoustic output indies on diagnostic ultrasound equipment.*
7) *NEMA UD 3-2004 (R2009), Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment*
8) *IEC 62133-2: 2017/AMD 2021, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems*
9) *FCC CFR TITLE 47 PART 15 SUBPART C SECTION 15.247*
10) *FDA 2023 guidance "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers : Guidance for Industry and Food and Drug Administration Staff"*

In volume accuracy test, the results show that the error is within ±7.5 mL when the measured volume is less than 100 mL, and the error is within ±7.5% when the measured volume is less than 999 mL. The range of measurement is between 0 to 999 mL.

A bladder boundary detection study (segmentation accuracy testing) shows that the bladder boundaries determined by ultrasound image match well with manually marked bladder boundaries. Using the Dice coefficient, the results of this quantitative evaluation passed the acceptance criteria.

Additionally, software verification and validation activities were performed to ensure the device performed as intended.

8.0 Clinical Study Summary

Clinical study is not performed for this product.

9.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device. Therefore, the subject device is substantially equivalent to the predicate device.