July 19, 2025

Jiangsu Tingsn Technology Co., Ltd.
Jing Wan
Regulatory Affairs
21st Floor, Building B, No. 3-1 Xinjinhu Road
Jiangbei New District
Nanjing, Jiangsu 210032
China

Re: K250913
Trade/Device Name: TINGSN FINDERS 2 Color Doppler Diagnostic Ultrasound System
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ, ITX, IYN, IYO
Dated: June 20, 2025
Received: June 20, 2025

Dear Jing Wan:

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,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
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.	K250913

Please provide the device trade name(s).

TINGSN FINDERS 2 Color Doppler Diagnostic Ultrasound System

Please provide your Indications for Use below.

TINGSN FINDERS 2 Color Doppler Diagnostic Ultrasound System is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult patients.
Modes of operation include: B,M, Color Doppler,PW Doppler, CW Doppler,Power Doppler; Combined modes: B/M,B/Color,B/M/Color, B/PWD, B/CWD, B/Color/PWD, B/Color/CWD, B/Power.
The device is intended for use in Professional healthcare facility environment including echo lab, other hospital settings, operating room, Cath lab and EP lab.
The intended users of the Device is to be used exclusively by physicians who are appropriately trained personnel in a fully equipped electrophysiology or catheterization room or under their direct supervision.

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

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

510(k) Summary

Submission: K250913

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. Sponsor Identification

Jiangsu Tingsn Technology Co., Ltd.
21st Floor, Building B,No.3-1 Xinjinhu Road,
Jiangbei New District, Nanjing, 210032, P.R. China

Contact Person: Jing Wan
Regulatory Affairs
Jiangsu Tingsn Technology Co., Ltd.
Tel: (+86) -18921028523
Email: wanjing@tingsn.com

Date prepared March 18, 2025

2. DEVICE

Device Name:	TINGSN FINDERS 2 Color Doppler Diagnostic Ultrasound System
Common name:	Ultrasonic Pulsed Doppler Imaging System
Regulation number	21 CFR 870.1200
Regulation Class:	Class II
Product Code:	OBJ,IYN,IYO,ITX

3. PREDICATE DEVICE

TINGSN FINDERS 2 Color Doppler Diagnostic Ultrasound System（The ultrasound console）：

Predicate Device：GE Vivid iq (K221148)

Reference Device：Clivia series Diagnostic Ultrasound System(K211886)

Common name:	Ultrasonic pulsed doppler imaging system
Regulation number	21 CFR 892.1550
Regulation Class:	Class II
Product Code:	IYN, IYO

TINGSN FINDERS 2 Color Doppler Diagnostic Ultrasound System (The ultrasound catheter)：

Predicate Device：SOUNDSTAR 3D Ultrasound Catheter(K092064)

Common name:	Catheter, ultrasound, intravascular
Regulation number	21 CFR 870.1200
Regulation Class:	Class II
Product Code:	OBJ

4. DEVICE DESCRIPTION

The proposed TINGSN FINDERS 2 Color Doppler Diagnostic Ultrasound System is a Track 3 diagnostic device designed for imaging intracardiac anatomical structures and blood flow dynamics in adult patients. It comprises two primary components: the ultrasound console and the TINGSN Sonic Eyes 10 Eco Disposable Intracardiac Echocardiography Catheter. The console features a 17.3-inch touch-enabled LCD screen, a control panel, and interfaces for connectivity, powered by a rechargeable battery or AC adapter, with optional peripherals including a cart and foot switch. The catheter, a sterile, single-use device with a 95 cm insertable length and 10Fr diameter, is equipped with a 64-element phased array transducer at its tip for high-resolution imaging. It connects to the console via the Finders 2 Sonic Eyes Connector, featuring a locking mechanism to ensure secure attachment during procedures. The system supports multiple imaging modes—B-Mode, M-Mode, Pulsed Wave (PW) Doppler, Continuous Wave (CW) Doppler, Color Doppler, Power Doppler, and combined modes —along with advanced functionalities, displayed with real-time thermal (TI) and mechanical (MI) indices.

5. INDICATIONS FOR USE

TINGSN FINDERS 2 Color Doppler Diagnostic Ultrasound System is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult patients.

Modes of operation include: B,M, Color Doppler,PW Doppler, CW Doppler,Power Doppler; Combined modes: B/M,B/Color,B/M/Color,B/PWD,B/CWD, B/Color/PWD, B/Color/CWD, B/Power.

The device is intended for use in Professional healthcare facility environment including echo lab, other hospital settings, operating room, Cath lab and EP lab.

The intended users of the Device is to be used exclusively by physicians who are appropriately trained personnel in a fully equipped electrophysiology or catheterization room or under their

direct supervision.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The TINGSN FINDERS 2 Color Doppler Diagnostic Ultrasound System, including its console and TINGSN Sonic Eyes 10 Eco Catheter, is compared to predicate devices (GE Vivid iq and SOUNDSTAR 3D Catheter) and a reference device (Clivia Series). The proposed device shares the same intended use, biocompatibility as the predicate devices and is similar in technological characteristics.

The TINGSN FINDERS 2 system, designed for intracardiac and intra-luminal imaging in adults, differs from the broader-ranging Vivid iq and SOUNDSTAR 3D Catheter predicates but is substantially equivalent, as its indications are encompassed by these devices.

Technical differences in imaging modes, software, and catheter length exist but do not impact safety or effectiveness. The system aligns with the predicates in core functions and principles, demonstrating substantial equivalence with no new risks.

Table 1: Comparison of the TINGSN FINDERS 2 Color Doppler Diagnostic Ultrasound System to the predicate device.

Description	**Proposed Device TINGSN FINDERS 2 Color Doppler Diagnostic Ultrasound System**	**Predicate Device vivid iq (K221148)**	**Reference Device Clivia series Diagnostic Ultrasound System （K211886）**	**Comments**
FDA Classification	Class II	Class II	Class II	Same
Product Code	IYN, IYO	IYN, IYO	IYN, IYO	Same
Regulation	21 CFR 892.1550	21 CFR 892.1550	21 CFR 892.1550	Same
Indications for use	TINGSN FINDERS 2 Color Doppler Diagnostic Ultrasound System is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as	The Vivid iq is high-performance compact diagnostic ultrasound system designed for cardiovascular and shared services.It is intended for use by Healtheare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid, Vivid iq clinical applications include: Fetal/Obstetrics, Abdominal (includes	The Clivia series Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It intended for use in	SE Analysis 1

	visualization of other devices in the heart of adult patients. Modes of operation include: B,M, Color Doppler,PW Doppler, CW Doppler,Power Doppler; Combined modes: B/M,B/Color,B/M/Color , B/PWD, B/CWD, B/Color/PWD, B/Color/CWD, B/Power. The device is intended for use in Professional healthcare facility environment including echo lab, other hospital settings, operating room, Cath lab and EP lab. The intended users of the Device is to be used exclusively by physicians who are appropriately trained personnel in a fully equipped electrophysiology or catheterization room or under their direct supervision.	GYN), Pediatric, Small Organ(includes breast, testes, thyroid), Neonatal Cephalic, Adult Cephalic, Cardiac (includes Adult and Pediatric), Peripheral Vascular, Musculoskeletal Conventional, Musculoskeletal Superficial, Urology (Including prostate), Transeranial, Transrectal, Transvaginal, Transesophageal, Interventional Guidance (including Biopsy), Thoracic/Pleural,Intraoperative(Vascular), Intracardiac and Intraluminal. Modes of operation include: B, M, PW Doppler, CW Doppler, Color Doppler, Color M, Power Doppler, Harmonic Imaging, Real-Time (RT) 3D Mode (4D), Coded Pulse and Combined modes: B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Color/CWD, B/Power/PWD. The device is intended for use in an indoor hospital environment including echo lab, other hospital settings, operating room, Cath lab and EP lab, in private medical offices, and in limited settings outside of professional Healthcare facilities.	Fetal/Obstetrics, Abdominal/GYN, Pediatrics, Small Organ(breast, thyroid, testes), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Thoracic/Pleural, Cardiac Adult, Cardiac Pediatric), peripheral vessel and Urology exams. The operator for Clivia series Diagnostic Ultrasound System is intended for professional clinical staff or the qualified and trained personnel with experience in the use of ultrasound diagnostic equipment. The device is intended to be used in hospital or clinics. Modes of operation include: B-Mode, M-Mode, Color	

			Mode, Power (Dirpower)-Mode, PW Doppler Mode, CW Doppler Mode, 3D/4D, Holo PW, Tissue Harmonic Imaging, Tissue Doppler Imaging(TDI), Anatomic M(AMM) and combined mode.	
Acoustic Output Track	Track 3	Track 3	Track 3	Same
Principle of operation	The TINGSN FINDERS 2 system employs Doppler ultrasound technology and ultrasound echo principles to simultaneously acquire information on blood flow dynamics, tissue motion, and organ structure imaging. When the ultrasound system is in operation, the transmission circuit converts electrical current through high-frequency oscillation into pulsed current, which is transmitted to the transducer at the tip of the ultrasound catheter. Utilizing the piezoelectric effect of the transducer crystal,	System console generates electrical current and sends to a connected, compatible transducer to stimulate its piezoelectric elements at the distal end. Stimulation causes the elements to expand and contract which creates a high-pressured wave . A series of soundwaves then propagate toward tissue medium (e.g., mucus membrane, bone). The transducer then receives echoed soundwaves that are reflected from the tissue medium and transmits it to the system. The system processes the echoed soundwaves into an image which is displayed on the display monitor screen of the system for user interpretation.	System console generates electrical current and sends to a connected, compatible transducer to stimulate its piezoelectric elements at the distal end. Stimulation causes the elements to expand and contract which creates a high-pressured wave . A series of soundwaves then propagate toward tissue medium (e.g., mucus membrane, bone). The transducer then receives	Same

	the pulsed current is transformed into ultrasound waves that are emitted. The same transducer crystal receives the reflected ultrasound waves and converts them back into electrical signals. The PC system processes the received echoes and displays a ultrasound image on the monitor, using varying brightness to represent echo strength.		echoed soundwaves that are reflected from the tissue medium and transmits it to the system. The system processes the echoed soundwaves into an image which is displayed on the display monitor screen of the system for user interpretation.	
Power Source	Ultrasound	Ultrasound	Ultrasound	Same
Configuration	Mobile cart with braking system	Mobile cart with braking system	Mobile cart with braking system	Same
Imaging modes	B, ,M, Color Doppler,PW Doppler, CW Doppler Power Doppler; Combined modes: B/M,B/Color,B/M/Color , B/PWD, B/CWD, B/Color/PWD, B/Color/CWD, B/Power.	B, M, PW Doppler, CW Doppler.Color Doppler, Color M, Power Doppler, Harmonic Imaging, Real-Time (RT) 3D Mode (4D), Coded Pulse and Combined modes: B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Color/CWD, B/Power/PWD.	B-Mode,M-Mode, Color Mode, Power (Dirpower)-Mode, PW Doppler Mode, CW DoppleMode, 3D/4D, Holo Pw, Tissue Harmonic Imaging, Tissue Doppler Imaging(TDI), Anatomic M(AMM) and combined mode.	SE Analysis 2

Type of compatible probes	ICE Probes（TINGSN Sonic Eyes 10 Eco Disposable Intracardiac Echocardiography Catheter）	Vivid iq utilizes a variety of electronic array transducers operating in linear, curved, sector/phased array, matrix array, or dual array format, including dedicated CW transducers and real time 3D transducer. The system can also be used with compatible ICE transducers.	Convex Array Intracavitary Probe (used transvaginally); Convex Array Probe (abdominal); Convex Volume Probe (abdominal); Linear Array Transducers (superficial peripheral vessels, small organs, peripheral vessels); Phased Array (cardiac).	SE Analysis 3
Primary Software features	One-click optimization (Auto) Line density Image enhancement Pseudo-color Smoothing Multi-focus synthesis* Grayscale mapping Frame correlation Wall filtering Color priority Color dual real-time* Edge enhancement Time-frequency resolution Tissue Doppler frequency spectrum imaging (TVD) Tissue Doppler imaging (TDI) Tissue velocity imaging (TVI)	Automatic EF (ejection fraction) Advanced cardiac measurements and analysis 4D/Multiplane LV measurement and analysis 4D Auto AVQ Composite imaging Advanced vascular measurements and analysis Pediatric calculations Obstetric measurements and calculations Quantitative analysis Measurements: depth, angle, distance, perimeter, area, time, slope, Doppler SV position, Doppler speed, Doppler angle correction	Tissue Doppler imaging (TDI), Tissue velocity imaging (TVI), Tissue Doppler frequency spectrum imaging (TVD), Anatomical M, 3D/4D imaging, Wide-angle imaging, Holo (plane wave PW) imaging, Image optimization features including gain, depth, TGC, image quality (frequency), sound power, focus, image display adjustment, line density, dynamic	SE Analysis 4

	Measurements: depth, distance, perimeter, area, slope, angle, heart rate, acceleration, time, velocity		range, image enhancement, frame correlation, rotation and mirror, spatial compound, grayscale mapping, pseudo-color, one-click optimization, wiNeedle, puncture-enhanced dual-window, time scale, display formats, edge enhancement, color gain, sample box adjustment, dual real-time, deflection, sensitivity, smoothing, scale, baseline, flip, waveform, wall filtering, color priority, trace lines, velocity, time/frequency resolution, display formats, duplex/triplex, angle correction, fast angle, volume, PW deflection, sample volume Measurements include: distance, perimeter, area, volume, angle,	

			depth, four-point three-line, hip joint angle, time, heart rate, slope, velocity, acceleration, spectrum, trace.	

Substantial Equivalence (SE) Analysis

SE analysis 1： **Indications for Use**

The Proposed Device is compatible only with the ICE catheter, which limits its application to intracardiac and intra-luminal ultrasound imaging. In contrast, the Predicate Device (Vivid iq) supports multiple probes, offering a broader range of applications. However, the Predicate Device also supports ICE catheters (e.g., the Soundstar 3D Ultrasound Catheter, AcuNav Diagnostic Ultrasound Catheter) for intracardiac and intra-luminal ultrasound imaging. Therefore, the Predicate Device's indications for use encompass those of the Proposed Device. They can be considered Substantially Equivalent (SE) in terms of safety and effectiveness, as no new risks are introduced, and the SE is not affected.

SE analysis 2： **Imaging Modes**

Both the Proposed Device and the Predicate Device share several key imaging modes, including B-mode, M-mode, Color Doppler, PW Doppler, CW Doppler, and Power Doppler. However, the Predicate Device supports additional imaging modes, including Real-Time 3D Mode (4D) , which are not present in the Proposed Device. Despite this difference, the essential imaging functions for cardiac and vascular diagnostics are supported in both devices. The inclusion of Real-Time 3D Mode (4D) in the Predicate Device does not introduce new risks or affect the safety and effectiveness of the Proposed Device. Therefore, this difference does not impact substantial equivalence, and both devices are substantially equivalent in terms of imaging modes.

SE analysis 3： **Type of Compatible Probes**

The Proposed Device is compatible only with ICE catheters, while the Predicate Device (Vivid iq) supports a wider variety of probes, offering more flexibility. However, the Predicate Device also supports ICE catheters, so the SE is not affected by this difference.

SE Analysis 4： **Primary Software features**

While the specific features differ, the Predicate Device’s software functions largely encompass the core functions of the Proposed Device, especially in terms of cardiac and vascular analysis,

Doppler imaging, and basic measurement tools. Therefore, the Predicate Device's software is sufficient to cover the functionality of the Proposed Device without leading to substantial differences in safety or effectiveness.A thorough risk analysis was conducted to assess potential risks related to software differences, particularly in the area of measurement accuracy and imaging performance. The risk mitigation strategies implemented during development ensure that the software functions of the Proposed Device meet the necessary safety and effectiveness standards, and any deviations from the Predicate Device's software features were carefully evaluated for potential impact on diagnostic performance.

Additionally, a Reference Device, the Clivia series Diagnostic Ultrasound System (K211886), has been introduced. Its software features cover the software features of the Proposed Device.

Therefore, we conclude that the differences between the software features of the Proposed Device and the Predicate Device do not introduce new risks that would compromise the safety or effectiveness of the device.

Table 2 Comparison of the proposed TINGSN Sonic Eyes 10 Eco Catheter to the currently marketed predicate device, the Soundstar 3d Ultrasound Catheter.

Description	Proposed Device TINGSN Sonic Eyes 10 Eco Catheters	Predicate Device The Soundstar 3d Ultrasound Catheter (K092064)	Comments
Classification	Class II	Class II	Same
Regulation	21 CFR 870.1200	21 CFR 870.1200	Same
Product code	OBJ	OBJ	Same
Indications for use	TINGSN FINDERS 2 Color Doppler Diagnostic Ultrasound System is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult patients. Modes of operation include: B,M, Color Doppler,PW Doppler, CW Doppler,Power Doppler; Combined modes: B/M,B/Color,B/M/Color, B/PWD, B/CWD, B/Color/PWD, B/Color/CWD, B/Power.	The Biosense Webster SOUNDSTAR 3D Diagnostic Ultrasound Catheter and related accessory devices are indicated for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with the CARTO XP EP Navigation System, Version 9.7 or greater, the SOUNDSTAR 3D Catheter provides location information.	SE Analysis 1

	The device is intended for use in Professional healthcare facility environment including echo lab, other hospital settings, operating room, Cath lab and EP lab. The intended users of the Device is to be used exclusively by physicians who are appropriately trained personnel in a fully equipped electrophysiology or catheterization room or under their direct supervision.		
Principle of operation	Catheter with ultrasound sensors that is used with an imaging system to display to provide high-resolution real-time visualization of cardiac structures, continuous monitoring of catheter location within the heart.	Catheter with ultrasound sensors that is used with an imaging system to display to provide high-resolution real-time visualization of cardiac structures, continuous monitoring of catheter location within the heart.	Same
Patient Population	Adult, not for fetal or pediatric use or for use in coronary vessels.	Adult, not for fetal or pediatric use or for use coronary vessels.	Same
Single Use	Yes	Yes	Same
Duration of Use	Limited (≤ 24 hours)	Limited (≤ 24 hours)	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Outside Diameter	10F	10F	Same
Insertable length	95cm	90cm	SE Analysis2
Deflection mechanism	Integrates a tip deflection mechanism using a deflection handle and pull-line to provide integrated 4-way deflection of catheter.	Integrates a tip deflection mechanism using a deflection handle and pull-line to provide integrated 4-way deflection of catheter.	Same
Transducer configuration	Multi-element linear phased array ultrasound transducer at distal tip	Multi-element linear phased array ultrasound transducer at distal tip	Same
Number of Ultrasound Transducer elements	64-channel acoustic phased array	64-channel acoustic phased array	Same

Ultrasound Imaging Frequency	4.5-9.5MHz	4-10 MHz	SE Analysis 3
Acoustic Output Track	Track 3 recommendations: the global maximum derated ISPTA should be ≤720 mW/cm^2 , and either the global maximum MI should be ≤1.9 or the global maximum derated ISPPA should be ≤ 190 W/cm^2.	Track 3 recommendations: the global maximum derated ISPTA should be ≤720 mW/cm^2 , and either the global maximum MI should be ≤1.9 or the global maximum derated ISPPA should be ≤ 190 W/cm^2.	Same
Imaging modes	B-Mode (2D only) M-Mode Doppler Pulsed Wave Doppler Continuous Wave Doppler Color Doppler (2D only) Power Doppler	B-Mode (2D only) M-Mode Doppler Pulsed Wave Doppler Continuous Wave Doppler Color Doppler (2D only) Power Doppler	Same
Patient contact materials(Catheter Shaft)	Pebax series Comply with ISO 10993-1	Pebax series Comply with ISO 10993-1	Same
Shelf life	2 years	1 Year	SE Analysis 4

Substantial Equivalence (SE) Analysis

SE analysis 1：**Indications for Use**

Both the Proposed and Predicate Devices are intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult patients. However, the Predicate Device's catheter tip is equipped with a position sensor that works with the CARTO system to provide location information, making its indications for use broader. This broader indication encompasses the use of the Proposed Device. Therefore, the Proposed Device does not introduce a new intended use, and its indications for use fall within those of the Predicate Device.

SE analysis 2：**Insertable Length**

The insertable length of the Proposed Device, like that of the Predicate Device, meets clinical requirements for a wide range of patients. This slight difference does not raise any concerns regarding safety or effectiveness.

SE analysis 3：**Ultrasound Imaging Frequency**

The Proposed Device has a narrower ultrasound frequency spectrum compared to the Predicate Device. However, both devices operate within the low-frequency ultrasound range, and the

Proposed Device's frequency range is adequate to meet the clinical requirements for intracardiac imaging. Therefore, this difference does not impact the safety or effectiveness of the device.

SE analysis 4：**Shelf Life**

The Proposed Device has undergone a 2-year shelf-life study, verifying product stability and packaging integrity. The claimed 2-year shelf life is scientifically reliable. These differences will not affect the safety and effectiveness of the Proposed Device.

7. PERFORMANCE DATA

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

TINGSN FINDERS 2 Color Doppler Diagnostic Ultrasound System conforms to the following standards:

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-37 2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 62359 2017 Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
- NEMA UD2 2004(2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3
- IS0 10555-1 2013 Intravascular catheters - Sterile and single-use intravascular catheters - Part 1: General requirements [Including AMENDMENT 1 (2017)]
- ISO 10993-1 2018, Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process
- ASTM D4169-2022 Standard Practice for Performance Testing of Shipping Containers and Systems

- ISO 14971: Medical devices- Applications of risk management to medical devices, 2019
- FDA Ultrasound Guidance document, "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers," issued in February 2023

Software documentation is included in accordance with the FDA guidance "Guidance for the Content of Premarket Submissions for Device Software Functions," issued on June 14, 2023. Non-clinical tests (integration and functional) were conducted on the TINGSN FINDERS 2 Color Doppler Diagnostic Ultrasound System during product development.

The risk analysis was completed and risk controls were implemented to mitigate identified hazards. The test results support that all the software specifications have met the acceptance criteria. Verification and validation testing were found acceptable to support the claim of substantial equivalence.

8. CLINICAL DATA

No clinical data was included in this submission.

9. CONCLUSION

The indications for use statement for the proposed device is similar to that of the predicate. While its indications are more focused on intracardiac and intra-luminal imaging, the Vivid iq and SOUNDSTAR 3D Catheter encompass these uses,the differences between the proposed device and its predicate device do not raise new issues of safety and effectiveness. The non-clinical data support the safety of the device and the performance testing report demonstrate that the TINGSN FINDERS 2 Color Doppler Diagnostic Ultrasound System should perform as intended in the specified use conditions.

From the results of non-clinical data including the performance testing described, Jiangsu Tingsn Technology Co., Ltd. concludes that the TINGSN FINDERS 2 Color Doppler Diagnostic Ultrasound System is as safe, as effective, and performs as well as the predicate devices (K221148 and K092064), and is therefore considered substantially equivalent to the predicate devices.