Esonic Technology (Wuhan) Co., Ltd.
Guo Dongyun
Regulatory Affairs Manager
Floor 7, Bldg. B1, Block B, Phase Ii, High-Tech Medical Devices Park, #818 Gaoxin Ave., E. Lake High-Tech Development Zone
Wuhan, Hubei 430000
China

July 23, 2026

Re: K261272
Trade/Device Name: ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Diagnostic ultrasound system
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX,
Dated: June 23, 2026
Received: June 23, 2026

Dear Guo Dongyun:

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: 2026.07.23 14:23:57 -04'00'

For Yanna Kang, Ph.D.
Assistant Director
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.	K261272

Please provide the device trade name(s).

ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Diagnostic ultrasound system

Please provide your Indications for Use below.

The ultrasound system is indicated for use in the following applications, for imaging and measurement of anatomical structures: Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Vascular, Peripheral Vascular, OB-GYN, Pelvic, Pediatric, Urology, Trans-rectal, Trans- vaginal and Neonatal/Adult Cephalic, Non-invasive Cardiac.

In addition, the ultrasound diagnostic system and associated transducers are intended for:
- Measurements of abdominal anatomical structures,
- Measurements of broad band shear wave speed, and tissue stiffness in internal structures of the liver and the spleen,
- Measurements of brightness ratio between liver and kidney,
- Visualization of abdominal vascularization, microvascularization and perfusion,

The shear wave speed, beam attenuation, viscosity and stiffness measurements, the brightness ratio, the visualization of vascularization, microvascularization and perfusion maybe used as an aid to clinical management of adult and pediatric patients with liver disease.

This device is intended for use by, or by the order of, and under the supervision of a licensed physician qualified to use or direct the use of the device.

This system should only be used by trained sonographers who are knowledgeable about the risk of excessive acoustic energy in the body, particularly in the case where a great amount of fluid is present in the scanning area. This device is intended to be used in a hospital or medical clinic.

Modes of operation include: B-Mode, M-mode, Color Doppler imaging, Pulsed Wave Doppler, Continuous Wave, Harmonic Imaging, Power Doppler imaging, Directional Power Doppler imaging, Contrast Enhanced Ultrasound Imaging, Elasticity Imaging and combined modes: B+ Color Flow, B+ Shear Wave Elastography, B+ Pulsed Wave, B+ Pulsed Wave + Color Flow, B+ M mode, B+ Continuous Wave.

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

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Classification

Add a primary product code and any associated product codes below. You may type in the primary product code directly (only the product code field is required) or you may filter down by choosing first a medical specialty, regulation, then product code. Please verify whether a device specific guidance or special control is available for the product code at the Product Classification website linked to below. The regulation should be consulted to determine if any special controls need to be considered (e.g. PAE and 21 CFR 890.3450). Use this website to verify information for associated product codes as well. ?

Medical Specialty	Radiology
Regulation	892.1550 - Ultrasonic pulsed doppler imaging system
Product Code	IYN (Class 2) - System, Imaging, Pulsed Doppler, Ultrasonic

Information about your primary product code, such as whether any applicable guidances or standards should be consulted, is available at the website below.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=IYN

Associated Product Code(s) IYO, ITX ?

K261272

510k Summary

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

1. Submitter's name, address, telephone number, contact person

Submitted by:
Manufacturer Name: eSonic Technology (Wuhan) Co., LTD
Address: Floor 7, Building B1, Block B, Phase II, High-tech Medical Devices Park, No.818 Gaoxin Avenue, East Lake High-tech Development Zone, Wuhan, Hubei, China

Primary Correspondent: Dongyun Guo/ Regulatory Affairs Manager
E-mail: registration@esonicimage.com
Telephone: (+86)13476081662

Date: 2026.4.16

2. Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Trade/Device Name: ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Diagnostic ultrasound system
Common Name: Diagnostic Ultrasound System
Regulatory Class: II
Review Panel: Radiology

Classification Name	21 CFR Section	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

3. Substantially Equivalent/Predicate Devices

AIXPLORER MACH 30 Ultrasound Diagnostic System (K191007).

4. Device Description

The proposed ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Diagnostic Ultrasound System are cart based ultrasound imaging system used to perform diagnostic

general purpose ultrasound imaging studies.
The system contains a scan converter and can be coupled to a variety of linear, convex, micro-convex and phased array transducers to produce images, which are displayed on a LCD monitor.
An adjustable control panel with integrated touch screen allows the user to perform an ultrasound exam quickly and efficiently in accordance with ALARA principles.
The system also allows the user to perform measurements and associated calculations, capture images to digital memory or to an external device (such as a printer), and review diagnostic studies in the form of a report.

5. Intended Use/Indications for Use

The ultrasound system is indicated for use in the following applications, for imaging and measurement of anatomical structures: Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Vascular, Peripheral Vascular, OB-GYN, Pelvic, Pediatric, Urology, Trans-rectal, Trans- vaginal and Neonatal/Adult Cephalic, Non-invasive Cardiac.

In addition, the ultrasound diagnostic system and associated transducers are intended for:

- Measurements of abdominal anatomical structures,
- Measurements of broad band shear wave speed, and tissue stiffness in internal structures of the liver and the spleen,
- Measurements of brightness ratio between liver and kidney,
- Visualization of abdominal vascularization, microvascularization and perfusion

The shear wave speed, beam attenuation, viscosity and stiffness measurements, the brightness ratio, the visualization of vascularization, microvascularization and perfusion may be used as an aid to clinical management of adult and pediatric patients with liver disease.

This device is intended for use by, or by the order of, and under the supervision of a licensed physician qualified to use or direct the use of the device.

This system should only be used by trained sonographers who are knowledgeable about the risk of excessive acoustic energy in the body, particularly in the case where a great amount of fluid is present in the scanning area. This device is intended to be used in a hospital or medical clinic.

Modes of operation include: B-Mode, M-mode, Color Doppler imaging, Pulsed

Wave Doppler, Continuous Wave, Harmonic Imaging, Power Doppler imaging, Directional Power Doppler imaging, Contrast Enhanced Ultrasound Imaging, Elasticity Imaging and combined modes: B+ Color Flow, B+ Shear Wave Elastography, B+ Pulsed Wave, B+ Pulsed Wave + Color Flow, B+ M mode, B+ Continuous Wave.

6. Summary of the technological characteristics- new device compared to the predicate device

The ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Diagnostic Ultrasound Systems and its predicate device, AIXPLORER MACH 30 Ultrasound Diagnostic System (K191007), have the equivalent intended use, and similar physical characteristics.

Description	**Subject Device** ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Diagnostic Ultrasound Systems	**Predicate Device** AIXPLORER MACH 30 Ultrasound Diagnostic System **(K191007)**	**Comments**
Indications for use	The ultrasound system is indicated for use in the following applications, for imaging and measurement of anatomical structures: Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Vascular, Peripheral Vascular, OB-GYN, Pelvic, Pediatric, Urology, Trans-rectal, Trans- vaginal and Neonatal/Adult Cephalic, Non-invasive Cardiac. In addition, the ultrasound diagnostic system and associated	The SuperSonic Imagine AIXPLORER MACH 30 ultrasound system is indicated for use in the following applications, for imaging and measurement of anatomical structures: Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Vascular, Peripheral Vascular, **Intraoperative**, OB-GYN, Pelvic, Pediatric, Urology, Trans-rectal, Trans-vaginal and Neonatal/Adult Cephalic, Non-invasive Cardiac. In addition, the SuperSonic Imagine AIXPLORER MACH 30 ultrasound diagnostic system and associated	Equivalent See **Note 1** **Note 3**

Description	Subject Device ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Diagnostic Ultrasound Systems	Predicate Device AIXPLORER MACH 30 Ultrasound Diagnostic System **(K191007)**	Comments
	transducers are intended for: • Measurements of abdominal anatomical structures, • Measurements of broad band shear wave speed, and tissue stiffness in internal structures of the liver and the spleen, • Measurements of brightness ratio between liver and kidney, • Visualization of abdominal vascularization, microvascularization and perfusion The shear wave speed, beam attenuation, viscosity and stiffness measurements, the brightness ratio, the visualization of vascularization, microvascularization and perfusion may be used as an aid to clinical management of adult and pediatric patients with liver disease.	transducers are intended for: • Measurements of abdominal anatomical structures, • Measurements of broad band shear wave speed, and tissue stiffness in internal structures of the liver and the spleen, • Measurements of brightness ratio between liver and kidney, • Visualization of abdominal vascularization, microvascularization and perfusion, • **Quantification of abdominal vascularization and perfusion** The shear wave speed, beam attenuation, viscosity and stiffness measurements, the brightness ratio, the visualization of vascularization, microvascularization and perfusion, **the quantification of vascularization and perfusion** may be used as an aid to clinical management of adult and pediatric patients with liver disease.	

Description	Subject Device ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Diagnostic Ultrasound Systems	Predicate Device AIXPLORER MACH 30 Ultrasound Diagnostic System **(K191007)**	Comments
	This device is intended for use by, or by the order of, and under the supervision of a licensed physician qualified to use or direct the use of the device. This system should only be used by trained sonographers who are knowledgeable about the risk of excessive acoustic energy in the body, particularly in the case where a great amount of fluid is present in the scanning area. **This device is intended to be used in a hospital or medical clinic.** **Modes of operation include: B-Mode, M-mode, Color Doppler imaging, Pulsed Wave Doppler, Continuous Wave, Harmonic Imaging, Power Doppler imaging, Directional Power Doppler imaging, Contrast Enhanced Ultrasound Imaging, Elasticity Imaging and combined modes: B+ Color Flow, B+ Shear Wave**	This device is intended for use by, or by the order of, and under the supervision of a licensed physician qualified to use or direct the use of the device. This system should only be used by trained sonographers who are knowledgeable about the risk of excessive acoustic energy in the body, particularly in the case where a great amount of fluid is present in the scanning area	

Description	Subject Device ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Diagnostic Ultrasound Systems	Predicate Device AIXPLORER MACH 30 Ultrasound Diagnostic System **(K191007)**	Comments
	Elastography, B+ Pulsed Wave, B+ Pulsed Wave + Color Flow, B+ M mode, B+ Continuous Wave.		
User	Qualified and trained healthcare professionals	Qualified and trained healthcare professionals	Same
Environment	Hospital or medical clinic	Hospital or medical clinic	Same
Design	Autocorrelation for color processing and FFT for pulse Doppler processing. Supporting Linear, Convex, Phase array probes.	Autocorrelation for color processing and FFT for pulse Doppler processing. Supporting Linear, Convex, Phase array probes.	Same
Patient Contact Materials	Material meet ISO 10993-1 and FDA guidance	Material meet ISO 10993-1 and FDA guidance	Equivalent **See Note2**
Mode of operation	Modes of operation include: B-Mode, M-mode, Color Doppler imaging, Pulsed Wave Doppler, Continuous Wave, Harmonic Imaging, *Power Doppler imaging, Directional Power Doppler imaging,* Contrast Enhanced Ultrasound Imaging, Elasticity Imaging. Combined modes: B+ Color Flow, B+ Shear Wave	Modes of operation include: B-Mode, M-mode, Color Doppler imaging, Pulsed Wave Doppler, Continuous Wave, Harmonic Imaging, *Amplitude Power Doppler imaging, Directional Amplitude Power imaging*, Contrast Enhanced Ultrasound Imaging, Elasticity Imaging and **3D imaging.** Combined modes: B+ Color Flow, B+ Shear Wave	Equivalent **See Note 3**

Description	Subject Device ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Diagnostic Ultrasound Systems	Predicate Device AIXPLORER MACH 30 Ultrasound Diagnostic System **(K191007)**	Comments
	Elastography, B+ Pulsed Wave, B+ Pulsed Wave + Color Flow, B+ M mode, B+ Continuous Wave.	Elastography, B+ Pulsed Wave, B+ Pulsed Wave + Color Flow, B+ M mode, B+ Continuous Wave, **B+Color flow +Shear wave Elastography, B+ M mode + Color flow, B + Strain + Shear Wave Elastography**	
Functions	➢ Tissue Harmonic Imaging ➢ *eCompound* (Spatial compounding) ➢ Panoramic imaging ➢ Biopsy guideline ➢ *Needle TS* ➢ ShearWave Elastography ➢ *Viscosity (dispersion nature of shear wave)* ➢ *ATI (attenuation imaging)* ➢ *QSOS(quantitative imaging of sound speed)* ➢ CFI, *PDI, dPDI* ➢ *iPlane PW* ➢ *iPlane Vascular (Color Doppler improvement)* ➢ TDI ➢ CEUS ➢ ECG ➢ *eTuner (Automatically adjust TGC)* ➢ *Optimize*	➢ Tissue Harmonic Imaging ➢ *SuperCompound (Spatial compounding)* ➢ Panoramic imaging ➢ Biopsy guideline ➢ *Needle PL.U. S* ➢ ShearWave Elastography ➢ *Vi PLUS (dispersion nature of shear wave)* ➢ *Att PLUS (attenuation imaging)* ➢ *SSp PLUS(quantitative imaging of sound speed)* ➢ CFI, *CPI, dCPI* ➢ *UltraFast™* ➢ *Angio PL.U.S (Color Doppler improvement)* ➢ TDI ➢ CEUS ➢ ECG ➢ *Auto (Automatically adjust TGC)* ➢ *Optimization*	Equivalent **See Note 4**

Description	Subject Device ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Diagnostic Ultrasound Systems	Predicate Device AIXPLORER MACH 30 Ultrasound Diagnostic System **(K191007)**	Comments
	➢ *Width* ➢ *eTissue* ➢ *eClear* ➢ *Expand (trapezoid)* ➢ USB ports ➢ Displayport ➢ CD/DVD Drive ➢ Printing ➢ Network(wired) ➢ DICOM ➢ *Dual/ Quad* ➢ Cine ➢ Bodymarker ➢ Annotation ➢ Report	➢ *Sector Size* ➢ *TissueTuner (Speed of Sound control)* ➢ *SuperRes (Adaptive Filtering)* ➢ *Wide Image (trapezoid)* ➢ USB ports ➢ Displayport ➢ CD/DVD Drive ➢ Printing ➢ Network(wired and **wireless**) ➢ DICOM ➢ *Dual-split/ Quad-split* ➢ Cine ➢ Bodymarker ➢ Annotation ➢ Report ➢ **Strain Elastography** ➢ **3D** ➢ **Barcode Scanner**	
Measurements	**Basic measurement:** ➢ **Measurement in B Mode:** distance, ellipse, trace, depth, volume, hip angle, d:D, IMT, B-mode ratio, % diameter reduction, % area reduction, distance ratio ➢ **Measurement in D Mode:** doppler time, PW autotrace, velocity, PSV/EDV, vessel diameter, doppler slope, doppler trace, Heart rate, TAMV, volume flow	**Basic measurement:** ➢ **Measurement in B Mode:** distance, ellipse, trace, depth, volume, hip angle, d:D, IMT, B-mode ratio, % diameter reduction, % area reduction, distance ratio ➢ **Measurement in D Mode:** doppler time, PW autotrace, velocity, PSV/EDV, **Doppler 2 Velocity Ratio**, vessel diameter, doppler slope, doppler time-slope,	Equivalent See **Note 5**

Description	Subject Device ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Diagnostic Ultrasound Systems	Predicate Device AIXPLORER MACH 30 Ultrasound Diagnostic System **(K191007)**	Comments
		doppler trace, TAMV, **congestion index**, Heart rate, volume flow ➢ **Measurement in M mode** Heart rate, M-distance, M time-slope ➢ **Measurement in E mode** *Q-BOX™, Q-BOX™ ratio, Q-BOX™ trace, MULTI Q-BOX™* **Measurement package:** ➢ Abdomen measurement package ➢ Gynecology measurement package ➢ Obstetric measurement package ➢ Cardiac measurement package ➢ Vascular measurement package ➢ Urology measurement package ➢ Small organ measurement package	
Transducer Types	Convex array Phased array Linear array Micro convex array	Convex array Phased array Linear array Micro convex array	Same
Acoustic Output within FDA	Track 3; Ispta.3 ≤ 720 mW/cm^2 MI ≤ 1.9	Track 3; Ispta.3 ≤ 720 mW/cm^2 MI ≤ 1.9	Same

Description	Subject Device ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Diagnostic Ultrasound Systems	Predicate Device AIXPLORER MACH 30 Ultrasound Diagnostic System **(K191007)**	Comments
guidelines	TI ≤ 6.0	TI ≤ 6.0	
General safety and effectiveness information	ANSI/AAMI ES60601-1 IEC60601-2-37 IEC60601-1-2 ISO 10993-1	ANSI/AAMI ES60601-1 IEC60601-2-37 IEC60601-1-2 ISO 10993-1	Same
Labeling	Conforms to 21 CFR Part 801	Conforms to 21 CFR Part 801	Same
Accessories	➢ Foot switch ➢ ECG cables ➢ Printer	➢ Foot switch ➢ ECG cables ➢ Printer ➢ **Displayport to HDMI, VGA and DVI adapter** ➢ **Barcode scanner** ➢ **Ethernet cable** ➢ **Wifi dongle** ➢ **Gels** ➢ **Sheaths** ➢ **Biopsy Guide** ➢ **Cleaners**	Equivalent See **Note 6**

Technology:

The ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Ultrasound Diagnostic System employs the same fundamental scientific technology as its predicate device.

Determination of substantial equivalence:

The Proposed ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Ultrasound Diagnostic System are substantially equivalent to the predicate AIXPLORER MACH 30 Ultrasound Diagnostic System (K191007) with regards to intended use, indication

for use, image capabilities, technological characteristics, image mode.
The following is an overview of the differences between the proposed Ultrasound Diagnostic System and its predicate device.

Comparison Analysis:

Note 1: Indications for use

The Indication for use of subject device does not support application of intraoperative, quantification of abdominal vascularization and perfusion, and not support operation modes of 3D imaging, B+Color flow +Shear wave Elastography, B+M mode+Color flow, B+Strain+Shear Wave Elastography. As the subject device does not support specific application and mode of operation or combined mode, it is less than predicate device. They can demonstrate substantial equivalence with predicate device.

Note 2: Patient Contact Materials

The Patient Contact Materials of probes is equivalent to the predicate device, both the subject and predicate device probe material meet ISO 10993-1 and FDA guidance requirement. They can demonstrate substantial equivalence with predicate device.

Note 3: Mode of operation

The subject device does not support operation modes of 3D imaging, B+Color flow +Shear wave Elastography, B+M mode+Color flow, B+Strain+Shear Wave Elastography. As the subject device does not support specific application and mode of operation or combined mode, it is less than predicate device. They can demonstrate substantial equivalence with predicate device.

Note 4: Functions

The subject device does not support functions of wireless, strain elastography, 3D and barcode scanner. As the subject device does not support specific functions, it is less than predicate device. And also functions eCompound (Spatial compounding), Needle TS, Viscosity (dispersion nature of shear wave), ATI (attenuation imaging), QSOS(quantitative imaging of sound speed), PDI, dPDI, iPlane PW, iPlane Vascular (Color Doppler improvement), eTuner, Optimize, Width, eTissue, eClear, Expand (trapezoid), Dual/ Quad of subject device are equivalent as SuperCompound (Spatial compounding), Needle PL.U. S, Vi PLUS, Att PLUS, SSp PLUS, CPI, dCPI, UltraFast™, Angio PL.U.S (Color Doppler improvement), Auto (Automatically adjust TGC), Optimization, Sector Size, TissueTuner (Speed of Sound control), SuperRes (Adaptive Filtering), Wide Image (trapezoid), Dual-

split/ Quad-split of predicate device respectively, just different name.
They can demonstrate substantial equivalence with predicate device.

Note 5: Measurements
The subject device does not support Doppler 2 Velocity Ratio, and congestion index. As the subject device function is less than Predicate device. And also Q-MEAS, Q- ratio, Q- MEAS trace, MULTI Q- MEAS of subject device are equivalent as Q-BOX™, Q-BOX™ ratio, Q-BOX™ trace, MULTI Q-BOX™ of predicate device respectively, just different name.
They can demonstrate substantial equivalence with predicate device.

Note 6: Accessories
The subject device does not support Accessories of Display port to HDMI, VGA and DVI adapter, Barcode scanner, Ethernet cable, Wifi dongle, Gels, Sheaths, Biopsy Guide, Cleaners. As the subject device accessories are less than predicate device, they can demonstrate substantial equivalence with predicate device.

The ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Ultrasound Diagnostic Systems employ the same fundamental scientific technology as its predicate device. The Proposed Ultrasound Diagnostic Systems are substantially equivalent to the predicate AIXPLORER MACH 30 (K191007) with regards to intended use, indication for use, image capabilities, technological characteristics, image mode. The patient contact materials, functions are demonstrated substantial equivalent with predicate device.

eSonic Technology (Wuhan) Co., LTD. believes that the ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Ultrasound Diagnostic Systems are substantially equivalent with the predicate device.

7. **A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence**

Summary of Non-clinical test:
The ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Ultrasound Diagnostic System were evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical

safety, and have been found to comply with applicable medical device safety standard. The Ultrasound Diagnostic System complies with voluntary standards:

(1) ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]

(2) IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION 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 Edition 3.0 2024-07 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

(5) IEC62359 Edition 2.1 2017-09 Ultrasonics-Field characterization- Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017.

(6) ISO10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

(7) ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

(8) ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization

(9) ISO10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation

(10) ISO14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices

(11) NEMA PS 3.1 - 3.20 2024e Digital Imaging and Communications in Medicine (DICOM) Set.

(12) IEC60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

(13) IEC62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices - Part 1: Application of usability engineering to medical devices

(14) IEC62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes

(15) ISTA 3E 2017 Similar Packaged-Products in Unitized Loads of Truckload Shipment

The above testing confirmed that ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Diagnostic Ultrasound System perform according to the stated intended use. All data fell within pre-determined product specifications and external standard requirements. Results of non-clinical testing confirmed the substantial equivalence of the Diagnostic Ultrasound System to the predicate device.
The performance tests of the Diagnostic Ultrasound System demonstrate substantial equivalence (SE) to the predicate device.

8. A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

Not Applicable. The subject of this premarket submission, did not require clinical studies to support substantial equivalence.

9. Conclusion

For testing, all pre-determined acceptance criteria were met. Results of these tests show that the proposed ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Diagnostic Ultrasound System meet their intended use.
The proposed ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Diagnostic Ultrasound System is similar to the predicate AIXPLORER MACH 30 (K191007) in terms of indications for use, design, technological characteristics, modes of operations. eSonic considers the ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Diagnostic Ultrasound System to be substantially equivalent, with respect to safety and effectiveness, to the predicate device.