October 27, 2026

Transonic Systems, Inc.
Katie Mason
Director of Regulatory Affairs
34 Dutch Mill Rd.
Ithaca, New York 14850

Re: K261714
Trade/Device Name: FlowXL® System: FlowXL Flowmeter and compatible Flowprobes and Flowsensors
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: September 24, 2026
Received: September 25, 2026

Dear Katie Mason:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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

Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

STEPHEN C. BROWNING -S

CDR Stephen Browning
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

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.

510(k) Number *(if known)*
K261714

Device Name
FlowXL® System: FlowXL Flowmeter and compatible Flowprobes and Flowsensors

Indications for Use *(Describe)*
Transonic's FlowXL Flowmeters, Flowprobes, and Flowsensors are intended as a secondary diagnostic device and are not intended for diagnostic purposes. They are indicated for use with adult and pediatric patients for the measurement of blood and liquid volume flow as follows:
• on major and peripheral arteries, veins, and ducts,
• on non-aerated synthetic vessel grafts,
• during open surgical procedures where surgery has already been medically indicated,
• at intraoperative sites which admit and retain ultrasonic couplant, such as sterile saline/ultrasonic gel couplant,
• where their application requires minimal vessel manipulation or constriction which could cause vessel spasm that would interfere with volume flow measurements,
• where their use does not unnecessarily lengthen surgical procedures.
Tubing flow measurements with the FlowXL and Flowsensors are indicated for use on flexible tubing during extracorporeal applications, (not on arteries or veins), and only for non-aerated media which is transparent to ultrasound.

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.

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510(k) SUMMARY - K261714

I. Submitter

Transonic Systems, Inc.
34 Dutch Mill Road,
Ithaca, NY 14850
Phone: +1 607.257.5300
Contact Person: Katie Mason
Email: Katie.Mason@Transonic.com
Date Prepared: October 23rd 2026

II. Device:

Proprietary Name: FlowXL® System: FlowXL Flowmeter with compatible Flowprobes and Flowsensors

Common Name: Transit-time Ultrasound Volume Flowmeter

Regulation Name: Ultrasonic Blood Flowmeter

Classification Name: Cardiovascular Blood Flowmeter

Regulation Number: 21 CFR 870.2100

Regulatory Class: Class II

Primary Product Code: DPW

Classification Panel: Cardiovascular

III. Predicate Device:

Primary Predicate: Transonic AureFlo System (K112657)

Classification Name: Cardiovascular Blood Flowmeter

Regulation Number: 21 CFR 870.2100

Primary Product Code: DPW

Device Class: Class II

Classification Panel: Cardiovascular

Reference Predicate: Transonic Flowmeter (K872048)

Classification Name: Cardiovascular Blood Flowmeter

Regulation Number: 21 CFR 870.2100

Primary Product Code: DPW

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Device Class: Class II

Classification Panel: Cardiovascular

IV. Device Description

The FlowXL Flowmeter is a touchscreen-based flow measurement platform that interfaces with compatible Flowprobes and Flowsensors to calculate and display real-time volumetric flow measurements and associated flow waveforms. The system includes two independent sensor ports that support simultaneous measurement from compatible Flowprobes and/or Flowsensors.

Compatible HS-Series Flowprobes are reusable, non-implantable transit-time ultrasound probes intended for intermittent intraoperative measurement of blood and liquid flow in exposed vessels, grafts, and ducts during open surgical procedures. Compatible HS-Series Flowsensors are reusable transit-time ultrasound sensors intended for extracorporeal tubing flow measurement applications.

The system provides mean volumetric flow as the primary measurement output together with a corresponding flow waveform. Optional waveform-derived parameters, including Pulsatility Index (PI), Diastolic/Systolic Ratio (D/S), and Diastolic Filling Percentage (DF%), may also be displayed depending on configuration and inputs. Mean flow and waveform visualization remain the primary basis for flow assessment. The system provides measurement data only and does not independently interpret clinical findings.

The FlowXL Flowmeter includes USB interfaces for data export/import, software updates, and optional printer connectivity. A DVI output supports optional secondary display connection, and an Ethernet interface supports post-procedure DICOM export. The system may optionally utilize a KeyCard feature for commercial activation of placed systems. The KeyCard functionality does not affect flow measurement operation or performance.

Reusable HS-Series FMC, FMV, and FME Flowprobes are provided non-sterile and are intended to be cleaned and sterilized prior to first use and between uses in accordance with the applicable Instructions for Use. The U.S. submission scope includes dynamic air removal steam sterilization only.

The FlowXL System follows the FDA Track 3 acoustic output framework for fixed-output devices. Acoustic output is controlled by fixed hardware and firmware parameters, is not user-adjustable, and remains below applicable display thresholds under IEC 60601-2-37.

V. Intended Use / Indications for Use

Intended Use:

FlowXL Flowmeter with Flowprobes:

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Transonic's FlowXL Flowmeters and Flowprobes use transit-time ultrasound technology to measure volume flow of blood and other liquids, and report derived parameters such as but not limited to Pulsatility Index, Diastolic Filling Percentage, and Diastolic/Systolic Ratio during surgical interventions.

FlowXL Flowmeter with Flowsensors:
Transonic's FlowXL Flowmeters and Flowsensors use transit-time ultrasound technology to measure volume flow of blood and other liquids during extracorporeal applications.

Indications for Use:
Transonic's FlowXL Flowmeters, Flowprobes, and Flowsensors are intended as a secondary diagnostic device and are not intended for diagnostic purposes. They are indicated for use with adult and pediatric patients for the measurement of blood and liquid volume flow as follows:

- on major and peripheral arteries, veins, and ducts,
- on non-aerated synthetic vessel grafts.
- during open surgical procedures where surgery has already been medically indicated,
- at intraoperative sites which admit and retain ultrasonic couplant, such as sterile saline/ultrasonic gel couplant,
- where their application requires minimal vessel manipulation or constriction which could cause vessel spasm that would interfere with volume flow measurements,
- where their use does not unnecessarily lengthen surgical procedures

Tubing flow measurements with the FlowXL and Flowsensors are indicated for use on flexible tubing during extracorporeal applications, (not on arteries or veins), and only for non-aerated media which is transparent to ultrasound.

VI. Comparison with Predicate Device

The FlowXL System, subject device of this submission is equivalent to the previously cleared primary predicate, AureFlo System (K112657), and the reference device Transonic Flowmeter (K872048) in terms of both the intended use and technological characteristics. The FlowXL System uses the same fundamental scientific technology as the primary predicate device.

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Category	Transonic FlowXL System (Subject Device)	Transonic AureFlo System (Primary Predicate, K112657)	Transonic Flowmeter (Reference Device, K872048)	Comparison
Intended Use	FlowXL Flowmeter, Flowprobes and Flowsensors use transit-time ultrasound technology to measure volume flow of blood and other liquids, and derived parameters thereof, during surgical interventions and extracorporeal applications.	AureFlo System uses transit-time ultrasound technology to measure volume flow of blood and other liquids, and derived parameters thereof, during surgical interventions and extracorporeal applications.	Transonic Flowmeters use transit-time ultrasound technology to measure volume flow of blood and other liquids, and derived parameters thereof, during surgical interventions and extracorporeal applications.	Same intended use and operating principle
Indications for Use	Transonic's FlowXL Flowmeters, Flowprobes, and Flowsensors intended as a secondary diagnostic device and are not intended for diagnostic purposes. They are indicated for use with adult and pediatric patients for the measurement of blood and liquid volume flow as follows: Perivascular flow measurements with the FlowXL and Flowprobes are indicated for use: • on major and peripheral arteries, veins, and ducts, • on non-aerated synthetic vessel grafts,	The AureFlo Monitor is intended for use with HT300 Series -FT Surgical Flowmeters. These Flowmeters are intended for use with adult and pediatric patients for measurement of blood and liquid volume flow with Transonic perivascular Flowprobes • on major and peripheral arteries, veins and ducts; • on non-aerated synthetic vessel grafts; • where surgery is medically indicated; intraoperatively, rather than in chronic implants; • at intraoperative sites which admit and retain ultrasonic couplant; with minimal vessel	K872048: Transonic R-Series and S Series ultrasonic perivascular Flowprobes apply ultrasound energy intraoperatively through a venous or arterial wall of an adult, pediatric, or fetal patient to measure the approximate instantaneous and average blood volume flow through exposed peripheral, splanchnic and for cardio-thoracic veins or arteries from 0.5 mm to 32 mm in diameter. Transonic clamp-on Flowprobes apply ultrasound energy (see specifications) through standard laboratory tubing to insonate adult, pediatric, or fetal patient blood or other liquid (i.e. saline, nutrient media, urine) to monitor the	Same indications for use, grammatical clarifications for ease in reading only, with added clarification that the FlowXL is not intended as a secondary diagnostic device.

Category	Transonic FlowXL System (Subject Device)	Transonic AureFlo System (Primary Predicate, K112657)	Transonic Flowmeter (Reference Device, K872048)	Comparison
	• during open surgical procedures where surgery has already been medically indicated, • at intraoperative sites which admit and retain ultrasonic couplant, such as sterile saline/ultrasonic gel couplant, • where their application requires minimal vessel manipulation or constriction which could cause vessel spasm that would interfere with volume flow measurements, • where their use does not unnecessarily lengthen surgical procedures, Tubing flow measurements with the FlowXL and Flowsensors are indicated for use on flexible tubing specific to the Flowsensor during extracorporeal applications, (not on arteries or veins), and only for non-aerated media which is transparent to ultrasound.	manipulation or constriction (to avoid vessel spasm); • where application does not unnecessarily lengthen surgical procedure. • Measurement of blood or perfusate volume flow with sterile tubing Flowsensors on flexible tubing specific to the Flowsensor (never on arteries, veins) and for non-aerated media which are transparent to ultrasound	approximate instantaneous and average volume flow.	
Patient Population	Adult and pediatric	Adult and pediatric	Adult and pediatric	Same as predicate
Main System Components	Flowmeter with integrated touchscreen display, Flowprobes, Flowsensors, optional Cart.	Flowmeter, Flowprobes, Flowsensors, Cart and Panel PC with touchscreen display.	Flowmeter, Flowprobes, Flowsensors, integrated strip chart printer (depending on model).	Same as primary predicate

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Category	Transonic FlowXL System (Subject Device)	Transonic AureFlo System (Primary Predicate, K112657)	Transonic Flowmeter (Reference Device, K872048)	Comparison
Configurations & Accessories	Cart, embedded touch screen Display, Secondary Display, Pole, or Tabletop Mounts, KeyCard for placed meter use, optional printer, ECG extension cable.	Cart, embedded touch-screen Display, Key for placed meter use, optional printer, ECG extension cable.	Cart (if used with AureFlo), LCD display, if not connected to AureFlo, Keys for placed meter use, embedded strip chart printer, ECG extension cable.	Similar to primary predicate device: minor differences relate to mounting options and do not affect measurement technology, performance, or intended use.
User Interface	Touchscreen display	Touchscreen display	LCD panel with buttons	Same as primary predicate device
Input	Flow channels (2), ECG, USB	Flow channels (1 or 2), ECG, USB	Flow channels (1 or 2), ECG, USB, pressure	Same as primary predicate device
Output	USB: for printers, import/export, updates DVI: for secondary display connection Ethernet: for DICOM export	USB: for printers, import/export, updates VGA: for connection of Flowmeter to touchscreen display	Analog BNC Output	Similar to primary predicate: same USB output; VGA output is a DVI output in the FlowXL. Ethernet output enables DICOM export. Differences do not affect measurement technology, performance or intended use.
Wireless Capabilities	No Wi-Fi connectivity, Near Field Communication (NFC) card reader for KeyCard recognition	No Wi-Fi connectivity, Wired Key activation	No Wi-Fi connectivity	Similar to predicate: differences do not affect measurement technology, performance, or intended use.
Power & Battery	Mains: 100-240V 50-60 Hz Type CF, Class I	Mains: 100-240V 50-60 Hz Type CF, Class I No battery	Mains: 100-240V 50-60 Hz Type CF, Class I No battery	Similar to primary predicate: FlowXL includes an auxiliary battery to support short-term power interruption; this does not affect device operation, measurement technology or performance

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Category	Transonic FlowXL System (Subject Device)	Transonic AureFlo System (Primary Predicate, K112657)	Transonic Flowmeter (Reference Device, K872048)	Comparison
	Auxiliary rechargeable Li-ion, 13.05 Vdc, 2.95 Ahr			
Flowsound	Yes	Yes	Yes	Same as predicate
Ultrasound Parameters	Frequency: 0.9-9.6 MHz	Frequency: 0.9-9.6 MHz	Frequency: 0.3-3.6 MHz	Similar to predicate, narrowed subset of probe included within this submission. Frequency ranges are comparable for probes of corresponding size and family.
Environment	Hospital	Hospital	Hospital	Same as predicate
Measured parameters	Mean & instantaneous flow	Mean & instantaneous flow	Mean & instantaneous flow	Same as predicate
Derived parameters (Flowprobes)	DF%, D/S ratio, PI	DF%, D/S ratio, PI	DF%, D/S ratio, PI	Same as predicate
System accuracy	±10% volume flow	±10% volume flow	±10% volume flow	Same as predicate
Flowprobes				
Patient contact and duration of use	Direct contact with tissue; Limited (<24h)	Direct contact with tissue; Limited (<24h)	Direct contact with tissue; Limited (<24h)	Same as predicate

Category	Transonic FlowXL System (Subject Device)	Transonic AureFlo System (Primary Predicate, K112657)	Transonic Flowmeter (Reference Device, K872048)	Comparison
Reuse	• Reusable, multi-patient	• Reusable, multi-patient • Single-use (MB, MBS Flowprobes)	• Reusable, multi-patient • Single-use (MB, MBS Flowprobes)	Same as predicate: only reusable Flowprobes are included within the scope of this submission.
Sterilization Method for Reusable Probes	Dynamic air removal steam sterilization, SAL 10^{-6}	Dynamic air removal steam sterilization, SAL 10^{-6}, H202 (Sterrad/Steris), EtO,	Dynamic air removal steam sterilization, SAL 10^{-6} , H202 (Sterrad/Steris), EtO.	Same as predicate: only dynamic air removal steam sterilization is included in this submission.
Flowprobe models and sizes	HS-series (FMV, FMC, FME) Sizes: 1.5 – 14mm	HQ-series FMV, FMC, FME, FSB, FTV, FTE, AU, MR, MRS, MB, MBS Sizes: 0.7 – 36	R-Series and S-Series, HQ-series FMV, FMC, FME, FSB, FTV, FTE, AU, MR, MRS, MB, MBS Sizes: 0.7 – 36	Similar to predicate: Limited probe models included in initial submission, probe geometry, materials, and specifications are comparable to predicates of corresponding size; differences relate primarily to cable length and connector configuration and do not affect the intended use or flow measurement technology.
Flowsensors				
Patient contact, duration of use, reuse, cleaning	No patient contact, reusable, provided non-sterile and are non-sterilizable	No patient contact, reusable, provided non-sterile and are non-sterilizable	No patient contact, reusable, provided non-sterile and are non-sterilizable	Same as predicate
Flowsensor models & Sizes	HSnXL-Series 1/8”-3/4”	HQnXL-Series 1/8” – 1 1/4”	HC-Series, HQnXL-Series 1/8” – 1 1/4”	Similar to predicate: Limited sensor models included in submission, probe geometry, materials, and specifications are comparable to predicates of corresponding size;

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Category	Transonic FlowXL System (Subject Device)	Transonic AureFlo System (Primary Predicate, K112657)	Transonic Flowmeter (Reference Device, K872048)	Comparison
				differences relate primarily to cable length and connector configuration and do not affect the intended use or flow measurement technology.

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VII. Substantial Equivalence Determination

The FlowXL System is substantially equivalent to the predicate AureFlo System (K112657) and Transonic Flowmeter (K872048); the subject and predicate devices share the same intended use, patient population, and fundamental technological principle of transit-time ultrasound flow measurement.

Like the predicate devices, the FlowXL System provides direct quantitative volume flow measurement and associated waveform visualization using transit-time ultrasound technology. The FlowXL System incorporates previously cleared transit-time flow measurement functionality and waveform visualization into a consolidated device architecture.

Differences between the subject and predicate devices relate primarily to system integration, user-interface implementation, mounting configurations, export features, and software architecture. These differences do not alter the intended use, fundamental operating principle, or primary performance characteristics of the device and do not raise new questions of safety or effectiveness.

VIII. Performance Testing

Clinical testing was not required to support the determination of substantial equivalence. Non-clinical bench testing was conducted to support substantial equivalence, which demonstrated that the FlowXL System met the applicable functional performance specifications. Bench testing included:

- Flow measurement accuracy verification,
- Waveform-derived parameter verification,
- Software verification and validation,
- Electrical safety testing,
- Electromagnetic compatibility testing,
- Acoustic output evaluation,
- Cybersecurity evaluation,
- Usability/human factors evaluation,
- Biocompatibility evaluation,
- Reprocessing validation.

Risk assessment for the FlowXL System was performed in accordance with ISO 14971:2019 Medical devices - Application of risk management to medical devices.

Electrical Safety & Electromagnetic Compatibility

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Electrical safety and electromagnetic compatibility testing were conducted in accordance with the standards listed below and demonstrated acceptable system performance and supported substantial equivalence to the predicate devices.

- ANSI/ AAMI 60601-1:2012/A1:2012/A2:2022, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance,
- IEC60601-1-2:2014+AMD1:2020, Medical Electrical Equipment- Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard; Electromagnetic Disturbances - Requirements and Tests
- IEC60601-2-37:2007+AMD1:2015 - Medical Electrical Equipment - Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment
- FDA Guidance on Electromagnetic Compatibility of Medical Devices, including Section J, Common Electromagnetic Emitters (2022).
- AIM 7351731, Rev 2 – Medical Electrical Equipment & System Electromagnetic Immunity Test for Exposure to RFID Readers.

Acoustic output characterization was performed in accordance with IEC 62359. The FlowXL System follows the FDA Track 3 acoustic output framework for fixed-output devices and remains below applicable display thresholds under IEC 60601-2-37. MI and TI values are less than 1.0 and thus do not require display.

Biocompatibility & Reprocessing

The Transonic FlowXL Flowmeter and HS-Series Flowprobes and Flowsensors have been evaluated for biocompatibility in accordance with applicable medical device safety standards:

- ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Reprocessing validation activities for reusable HS-Series FMC, FMV, and FME Flowprobes included cleaning, steam sterilization, and repeated-use durability evaluation after the maximum uses in accordance with the applicable Instructions for Use and were designed in accordance with FDA Guidance on Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (2015) and ISO 17664-1 :2021-1 Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices Part 1 Critical and semi-critical medical devices. Biocompatibility testing was performed after maximum reprocessing.

Human Factors

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Both the Transonic FlowXL Flowmeter and HS-Series Perivascular Flowprobes were evaluated in accordance with applicable usability engineering standards, including IEC 62366-1:2015+AMD1:2020 Medical devices - Part 1: Application of usability engineering to medical devices and FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices, 2016.

Software and Cybersecurity

Software verification and validation activities demonstrated that the FlowXL System performed as intended and supported substantial equivalence to the predicate devices. The FlowXL was designed in accordance with IEC 62304 requirements.

The FlowXL was developed in consideration of applicable FDA guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions", including threat modeling, vulnerability testing, and independent penetration testing.

IX. Conclusion

The FlowXL System has the same intended use and fundamental technological characteristics as the predicate devices.

Differences between the subject and predicate devices relate primarily to system integration, user-interface implementation, mounting configurations, export features, and software architecture, and do not raise new questions of safety or effectiveness.

The nonclinical testing supports Transonic's conclusion that the FlowXL System is substantially equivalent to the predicate devices and is as safe and effective as the legally marketed predicate devices when used as labeled.