May 6, 2026

Intervention Tech, Inc. ; dba Corvention
% Natasha Bond
Regulatory Consultant to Corvention
Ikigai Medical Development
2198 Zinnia Way
Golden, Colorado 80401

Re: K253855
Trade/Device Name: KardiaPSI™
Regulation Number: 21 CFR 870.1255
Regulation Name: Balloon Aortic Valvuloplasty Catheter
Regulatory Class: Class II
Product Code: OZT
Dated: April 6, 2026
Received: April 6, 2026

Dear Natasha Bond:

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,

For JULIE B. MACKEL -S

Digitally signed by JULIE B. MACKEL -S
Date: 2026.05.06 15:34:56 -04'00'

Jennifer Kevit, PhD
Acting Assistant Director
DHT2B: Division of Circulatory Support, Structural, and Vascular Devices
OHT2: 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)*
K253855

Device Name
KardiaPSI™ Balloon Catheter

Indications for Use *(Describe)*
The KardiaPSI™ Balloon Catheter is indicated for Balloon Aortic Valvuloplasty.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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KardiaPSI™ Balloon Catheter 510(k) Summary

Applicant Contact Details (refer 21 CFR 807.92(a)(1):

Applicant Name:	Intervention Tech, Inc; dba Corvention
Applicant Address:	2201 N. Gemini Dr, Ste 138
Applicant Contact Phone #	928-707-4031
Applicant Contact:	Mr. Ryan Smith, Vice President of Engineering
Applicant Contact email	rsmith@corvention.com

Subject Device (refer 21 CFR 807.92(a)(2)):

Trade Name:	KardiaPSI™ Balloon Catheter
Common Name	Valvuloplasty Balloon Catheter
Classification Name	Balloon Aortic Valvuloplasty Catheter
Submission #	K253855
Submission Type	Traditional 510(k)
Product Regulation #:	21-CFR-870.1255
Product Code:	OZT

Legally Marketed Predicate Device (refer 21 CFR 807.92(a)(3)):

Predicate 510(k)#:	K122012
Predicate Trade name:	Z-Med & Z-Med-II Balloon catheters
Predicate Sponsor:	B. Braun
Predicate Product Code:	OZT

Device Description (refer 21 CFR 807.92(a)(4)):

The KardiaPSI™ Balloon Catheter is an over-the-wire coaxial catheter with a non-compliant balloon fixed at the distal tip. The catheter working length is 120cm long and has two lumens: one lumen is used to inflate and deflate the balloon (closed ended) and the other permits the use of a guidewire to position the catheter (open ended). The balloon inflation luer-lock hub (angled) connects to a currently marketed third-party syringe inflation device to deliver radiopaque contrast media (diluted with saline) for inflation. The guidewire luer-lock hub (straight) connects to the guidewire lumen. The balloon is non-compliant and is designed to reach a known diameter and length when inflated to the specified nominal inflation pressure of 4ATM (common across all sizes of balloons in the product matrix). Two radiopaque marker bands are provided for fluoroscopic positioning of the device across the aortic valve. These bands are positioned at the proximal and distal balloon shoulders.

Intended Use / Indication for Use (refer 21 CFR 807.92(a)(5)):

The KardiaPSI™ Balloon Catheter is indicated for Balloon Aortic Valvuloplasty.

Indication for Use Comparison (refer 21 CFR 807.92(a)(5)):

A comparison of the characteristics of the proposed device and the predicate device shows there are no differences between the subject device and the predicate device with respect to clinical aspects, indications and intended use. Both devices have the same principle and mechanism of operation. The KardiaPSI™ Balloon Catheter is determined to be substantially equivalent to the predicate device.

Technological Comparison (refer 21 CFR 807.92(a)(6)):

Technological aspects were assessed for substantial equivalence. The subject device is available in a range of sizes that are completely within the dimensional range of the sizes offered by the predicate device for both catheter and balloon dimensions. The shape, materials of construction and manufacturing processes are similar to the predicate device. The catheter configuration, user interface and nominal inflation pressures are all comparable to predicate. The balloon rated burst pressure for the subject device is greater than for the predicate. This technological difference has been tested against the recognized methods per ISO10555-4:2023 and does not raise new questions of safety or effectiveness.

Non-Clinical and / or Clinical Tests Summary & Conclusions (refer 21 CFR 807.92(b)):

Bench Verification for the catheter including dimensional verification, kink, tensile, corrosion, fluoroscopy, simulated use and user validation, per ISO 10555-1: 2023 and ISO 10555-4: 2023.

Bench verification for the balloon included dimensional, inflation, deflation, fatigue and rated burst. per ISO 10555-1: 2023 and ISO 10555-4: 2023.

Sterility Validation per ISO 11135: 2014. Sterile barrier packaging effectiveness was confirmed per ISO 11607-1:2019.

Biocompatibility testing was completed:

- Cytotoxicity per ISO-10993-5
- Sensitization per ISO-10993-10
- Intracutaneous Reactivity per ISO-10993- 23
- Systemic Toxicity per ISO-10993-11
- Pyrogenicity per USP <151>
- Hemolysis per ISO-10993-4
- Complement Activation per ISO-10993-4
- Partial Thromboplastin Time per ASTM F2382
- Platelet & Leukocyte Count Assay per ASTM F2888
- In Vivo Thromboresistance Study per ISO-10993-4

Conclusion:

Corvention considers the KardiaPSI™ Balloon Catheter to be substantially equivalent to the predicate device. This conclusion is based upon the fact that the devices have identical Intended Use, and there are no clinical, technical or biological differences that, when tested against recognized consensus standards, raise new questions of safety or effectiveness. Nonclinical testing demonstrated that the KardiaPSI™ Balloon Catheter performs substantially similar to the predicate device, except in providing a higher rated burst pressure and does not introduce new questions of safety or effectiveness.