August 18, 2026

Wallaby Medical
Rachel McDaid
Senior Regulatory Affairs Specialist
22901 Mill Creek Drive
Laguna Hills, California 92653

Re: K254071
Trade/Device Name: p17 XR Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: July 16, 2026
Received: July 16, 2026

Dear Rachel McDaid:

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,

NAIRA MURADYAN -S

Naira Muradyan, PhD
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine 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.	K254071

Please provide the device trade name(s).

p17 XR Microcatheter

Please provide your Indications for Use below.

The p17 XR Microcatheter is indicated for use with compatible accessories in the delivery of interventional and therapeutic devices and infusion of diagnostic agents, such as contrast media, into the peripheral and neuro vasculature. It is not intended for use in coronary vasculature.

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

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

K254071 510(k) Summary (21 CFR 807.92)

I. SUBMITTER

Wallaby Medical
22901 Mill Creek Drive,
Laguna Hills, California 92653

Contact Person: Rachel McDaid
Phone: +353 (0)91 740128
Date Prepared: July 16th, 2026

II. DEVICE

Device Tradename: p17 XR Microcatheter
Common or Usual Name: Percutaneous Catheter
Classification: Class II device according to 21 CFR 870.1250 (Percutaneous catheter)
Product Codes and Review Panel:

Product Codes	QJP (primary), DQY (secondary)
Review Panel	Cardiovascular

III. PREDICATE DEVICE

Name of Predicate Device: Headway 17 Advanced Microcatheter
Name of Predicate Device Manufacturer: MicroVention, Inc.
510(k) number of Predicate Device: K101542

IV. DEVICE DESCRIPTION

Device Description:

The p17 XR Microcatheter is a 0.017" inner diameter (ID) single lumen microcatheter with working length of 150 cm or 160 cm. The inner lumen is lined with a polytetrafluoroethylene (PTFE) liner, and the outer layer consists of Pebax of varying durometers and polyamide. The outer distal 60 cm is coated with a hydrophilic coating. Between the polymer layers and the PTFE liner there is a stainless-steel coil which extends throughout the entire device shaft, and a nitinol braid over the stainless-steel coil in the proximal section of the device shaft. The distal tip of the microcatheter has either one or two radiopaque platinum-iridium marker bands depending on device configuration. The proximal end of the device contains an injection molded Trogamid hub and Pebax strain relief.

The p17 XR Microcatheter is a non-active, surgically invasive device intended for limited duration use within the vasculature.

Environment of Use:

The p17 XR Microcatheter is intended to be used in a healthcare facility/hospital by trained physicians only.

V. INDICATIONS FOR USE

Table 1: Comparison of Indications for Use of the p17 XR Microcatheter with the predicate device

Parameter	Predicate Device Headway 17 Advanced Microcatheter K101542	Subject Device p17 XR Microcatheter K254071
Indications for Use	The Headway 17 Advanced Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.	The p17 XR Microcatheter is indicated for use with compatible accessories in the delivery of interventional and therapeutic devices and infusion of diagnostic agents, such as contrast media, into the peripheral and neuro vasculature. It is not intended for use in coronary vasculature.

The subject device has a subset of the predicate's intended use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 2: Comparison of technological characteristics of the p17 XR Microcatheter and predicate device Headway 17 Advanced Microcatheter

Parameter	Predicate Device K101542	Subject Device K254071
Device Name	Headway 17 Advanced Microcatheter	p17 XR Microcatheter
Model #	MC172150SX	MC171501 MC171601 MC171502 MC171602
Product Classification	21 CFR 870.1250 Class II	21 CFR 870.1250 Class II
Product Code	DQY	QJP, DQY
Device Design/Materials	Stainless steel coil, polymeric exterior, two marker bands	Stainless steel coil, nitinol braid, polymeric exterior, 1 or 2 marker bands
Marker Band Material/ Radiopacity	Radiopaque Platinum/Iridium	Radiopaque Platinum/Iridium
Hub Material	Nylon (polyamide)	Polyamide
Coating	Hydrophilic coating Length: 100cm	Hydrophilic coating Length: 60cm
Mode of Action	Physical	Physical
Working Length	150cm	150cm, 160cm
Outer Diameter	0.022” Distal 0.031” Proximal	0.025” Distal Tip 0.029” Proximal
Inner Diameter	0.017”	0.017”
Use	Single Use Device	Single Use Device
Sterilization	Ethylene Oxide	Ethylene Oxide
Biocompatible	Yes	Yes
Shelf Life	3 years	12 months
Accessory Devices	Introducer Sheath, Shaping Mandrel	Introducer Sheath, Shaping Mandrel, Rotating Hemostasis Valve(RHV)
Packaging Components/ Configuration	Device is stored within a packaging hoop sealed within a Tyvek to Nylon pouch, which is then packaged in a product carton.	Device is stored within a packaging hoop sealed within a Tyvek to Nylon pouch, which is then packaged in a product carton.

VII. PERFORMANCE DATA

Biocompatibility

Biocompatibility testing for the p17 XR Microcatheter was conducted based on International Organization for Standardization (ISO) 10993-1:2018 "Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process," and the US FDA guidance document "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process"" (2023).
Non-clinical bench testing has been conducted to evaluate compatibility of the p17 XR Microcatheter with dimethyl sulfoxide (DMSO), Onyx LES and SQUID liquid embolic agents.

Table 3 below summarizes biocompatibility testing performed on the p17 XR Microcatheter and accessories included with the device.

Table 3: Biocompatibility Testing Results for p17 XR Microcatheter

Test	Test Description	Conclusion
p17 XR Microcatheter (including Shaping Mandrel) Test Results		
Cytotoxicity ISO 10993-5	ISO MEM Elution Cytotoxicity	No cytotoxic effect.
Irritation or Intracutaneous Reactivity ISO 10993-23	ISO Intracutaneous Irritation	No irritation indicated.
Sensitization ISO 10993-10	ISO Guinea Pig Maximization Sensitization	No sensitization indicated.
Systemic Toxicity ISO 10993-11	ISO Acute Systemic Toxicity	No acute systemic toxicity indicated.
	ISO Materials Mediated Rabbit Pyrogen	p17 XR is deemed non- pyrogenic.
Hemocompatibility ISO 10993-4	Complement Activation	No complement activation indicated.
	ASTM Hemolysis - Direct Contact and Extract Method	No hemolysis indicated.
	Thromboresistance Evaluation	p17 XR is deemed comparable to the predicate.
	ISO Heparinized Blood Platelet and Leukocyte Count Assay with Comparison Article	p17 XR is deemed comparable to the predicate.
	ISO Partial Thromboplastin Time (PTT) Assay with Comparison Article	p17 XR is deemed comparable to the predicate.
Accessory Test Results - Introducer Sheath		
Cytotoxicity ISO 10993-5	ISO MEM Elution Cytotoxicity	No cytotoxic effect.
	MTT	No cytotoxic effect.
Sensitization ISO 10993-10	ISO Guinea Pig Maximization	No sensitization indicated.

	Sensitization	
Irritation or Intracutaneous Reactivity ISO 10993-10	ISO Intracutaneous Reactivity	No irritation indicated.
Systemic Toxicity ISO 10993-11	ISO Acute Systemic Toxicity	No acute systemic toxicity indicated.
	USP Material Mediated Pyrogenicity test	Test articles are deemed non-pyrogenic.
Hemocompatibility ISO 10993-4	ASTM Hemolysis - Direct Contact and Extract Method	No hemolysis indicated.
Accessory Test Results - Rotating Hemostasis Valve		
Cytotoxicity ISO 10993-5	ISO MEM elution Cytotoxicity	No cytotoxic effect.
Hemocompatibility ISO 10993-4	ASTM Hemolysis - Direct Contact and Extract Method	No hemolysis indicated.
Irritation or Intracutaneous Reactivity ISO 10993-10	ISO Intracutaneous Reactivity	No irritation indicated.
Systemic Toxicity ISO 10993-11	ISO Acute Systemic Toxicity	No acute systemic toxicity indicated.
	ISO Materials Mediated Rabbit Pyrogen	RHV is deemed non- pyrogenic.
Sensitization ISO 10993-10	ISO Guinea Pig Maximization Sensitization	No sensitization indicated.

Sterilization

The p17 XR Microcatheter is sterilized by Ethylene Oxide gas. Sterilization takes place in Steris Sterilization Technologies (Suzhou) Ltd., Jiangsu, China.

The p17 XR Microcatheter has been adopted into an existing validated cycle per EN ISO 11135:2014 and AAMI TIR28:2009.

Standards utilized in regards to Sterilization:
ISO 11135:2014 "Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices"
FDA Guidance Documents utilized in regards to Sterilization:
"Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labelled as Sterile" (2016)

The sterilization cycle has been validated via the overkill method.

Shelf Life

Shelf life conditioning has been completed and testing has been performed on devices subjected to the accelerated aging (AA) process to represent 1 year of aged units. Devices subjected to 1 year AA were tested in non-clinical bench testing.

FDA Guidance Documents utilized in regards to Shelf Life:

“Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling” (2019)

“Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters - Class II Special Controls Guidance for Industry and FDA” (2010)

"Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings - Labeling Considerations" (2019)

Non-Clinical Performance Data

The following non-clinical performance tests were performed to support the substantial equivalence determination. These are summarized below.

PERFORMANCE TESTING - BENCH

A full suite of performance testing on the bench was carried out on p17 XR Microcatheter. The results of this testing demonstrated compliance to all the design attributes and that the device performs as intended. The results of these tests, in conjunction with the substantial equivalence claims as outlined in the premarket notification, demonstrate substantial equivalence to the cited predicate device. Table 4 below summarizes the tests and results.

Table 4: Summary of Non-Clinical Bench Testing

Test Attribute	Test Method Summary	Result
Dimensional Verification (Working Length, Inner Diameter (ID), Outer Diameter(OD))	The dimensions of the catheter, shaping mandrel and introducer sheath are measured.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Navigability	The device is tested for its ability to reach target site in an anatomical model.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Kink Resistance	The catheter is tested at different locations for its ability to bend to clinically relevant radii without kinking.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Coating Lubricity	The catheter's hydrophilic coating lubricity is tested by applying a force to the coated section of the catheter. The friction force shall be equal to or below the specified maximum friction values.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended. This is comparable to the predicate device, thus supporting substantial equivalence.
Coating Integrity	The coated length of device is inspected for defects post simulated use.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.

Test Attribute	Test Method Summary	Result
Delivery and Retrieval Friction	The device is tested for its ability to deliver and retract a interventional device from a target site in an anatomical model below a specified force.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended. This is comparable with the predicate device, thus supporting substantial equivalence
Torque	The catheter was evaluated for torque strength by rotating the test sample within an anatomical model. The catheter must exceed a specified minimum number of rotations.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended. This is comparable with the predicate device, thus supporting substantial equivalence.
Tip Stiffness	The catheter tip is tested by bending it under a specified force.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended. This is comparable with the predicate device, thus supporting substantial equivalence
Stability	Device shall maintain placement in a tortuous model during the delivery of an interventional device.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Atraumatic Tip	The microcatheter tip shall be smooth, rounded.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Marker Band Radiopacity	The marker bands on the microcatheter shall be visible under fluoroscopy.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Tip Shapeability	The distal tip of the microcatheter must be able to hold shape after tip shaping, and tip shaping should not damage the microcatheter.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Peelable Introducer Sheath	Peelable introducer sheath must be able to fit over the microcatheter tip without damaging the microcatheter, and peelable sheath must be able to peel away.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Compatibility – Interventional Devices	An appropriately sized guidewire is delivered and retrieved through the microcatheter. The microcatheter is delivered and retrieved through an appropriately sized guide catheter.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Chemical Compatibility	The microcatheter shall resist damage when exposed to saline and contrast media.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended

Test Attribute	Test Method Summary	Result
Compatibility – DMSO	The microcatheter shall resist damage and maintain mechanical integrity after extended DMSO exposure.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Surface Defects	The microcatheter is examined under magnification for extraneous matter.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Peak Shaft and Hub Tensile	The catheter is tested at different locations under tensile force to meet a pre-determined specification.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Liquid Leak	The catheter is tested for leakage under a specified static pressure for a specified time.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended
Air Leak	The catheter is tested for air leakage for a specified time.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Hub Compatibility	The catheter hub is tested per ISO 80369-7.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Static Burst	The catheter is tested to withstand a specified static pressure.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Dynamic Burst	The catheter is tested to withstand a specified power injection pressure and to characterize flow rates and pressures during delivery of fluids.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Corrosion	The device and shaping mandrel are visually inspected for signs of corrosion post exposure to required conditions.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Particulate Testing	The catheter particulate matter is tested by calculating the size and number of particulates generated during simulated use of the device in a neurovascular model.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended. This was comparable to the predicate device, thus, supporting substantial equivalence.

Standards utilized in regards to Bench Testing:
ISO 10555-1:2023 "Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements"
ISO 80369-20:2015(E) "Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods"
ISO 80369-7:2021(E) "Small-bore connectors for liquids and gases in healthcare application - Part 7: Connectors for intravascular or hypodermic applications"
IEC 62366-1: 2015/AMD1:2020 "Medical Devices- Part 1: Application of Usability Engineering to Medical Devices"

FDA Guidance Documents utilized in regard to Bench Testing:
"Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019)
"Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters - Class II Special Controls Guidance for Industry and FDA" (2010)
"Applying Human Factors and Usability Engineering to Medical Devices" (2016)

Clinical Testing
Clinical testing was not performed on the p17 XR Microcatheter as no human studies were deemed necessary to establish substantial equivalence.

Animal Testing
An animal study was not deemed necessary to support the substantial equivalence of the subject device to the predicate device. Bench testing was determined sufficient to support substantial equivalence.

VIII. CONCLUSIONS

Wallaby Medical has demonstrated that the p17 XR Microcatheter is substantially equivalent to the predicate Headway 17 Advanced Microcatheter (K101542). The subject device has the same intended use, similar technological characteristics, similar materials, and the same operating principle as the predicate device. The differences do not raise new questions of safety or effectiveness. The subject device has been demonstrated to perform as intended through successful non-clinical performance testing.