May 20, 2026

WAVE Medical AG
Kym Rupp
Regulatory Consultant to WAVE Medical AG
Industrieplatz 1e
Bldg. 53
Neuhausen Am Rheinfall, Switzerland 8212

Re: K260304
Trade/Device Name: WAVE PTA Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: April 20, 2026
Received: April 21, 2026

Dear Kym Rupp:

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,

GREGORY W. O'CONNELL -S
Digitally signed by GREGORY W. O'CONNELL -S
Date: 2026.05.20 08:34:59 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention 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)*
K260304

Device Name
WAVE PTA Balloon Catheter

Indications for Use *(Describe)*
The WAVE PTA Balloon Catheter is indicated to dilate stenoses in femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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.

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510(k) Summary

This 510(k) summary information is prepared in accordance with 21 CFR §807.92.

Date Prepared:	January 30, 2026	
Manufacturer:	WAVE Medical AG Industrieplatz 1e 8212 Neuhausen am Rheinfall Switzerland	
Consultant Preparer:	Kym Rupp Regulatory Consultant to WAVE Medical Phone: 407-756-0035 E-mail: kym.rupp@gmail.com	
510(k) Owner and Business Contact	Jana Brandtner Vice President QA/RA Phone +41 79 942 17 51 E-mail: jana.brandtner@ctivascular.ch	
Device Name:	WAVE PTA Balloon Catheter	
Classification:	Classification Name:	Percutaneous catheter
	Classification Regulation:	21CFR §870.1250
	Classification Panel:	Cardiovascular
	Device Class:	Class II
	Product code:	LIT (Percutaneous Catheter)
Predicate Device:	Trade Name:	Armada 14 PTA Catheter
	Manufacturer:	Abbott Vascular
	510(k) Clearance:	K102705
	Classification Regulation:	21 CFR, Part 870.1250
	Classification Name:	Percutaneous catheter
	Classification Panel:	Cardiovascular
	Device Class:	Class II
	Product Code:	LIT (Percutaneous Catheter)

Predicate Comparison:

Device Name	Predicate Device	Subject Device
	Armada 14 PTA Catheter	**WAVE PTA Balloon Catheter**
Catheter Type	Over-the-Wire	Over-the-Wire
Shaft Construction	Coaxial	2-lumen Shaft
Guidewire Compatibility	0.014" (0.36 mm)	0.014" (0.36 mm)
Sheath Compatibility	4F	4F or larger
Nominal Pressure	8 atm	8 atm
Rated Burst Pressure (RBP)	14 atm	14 atm
Contrast Infusion	No	No
Coating	Hydrophobic	Hydrophobic
Coating Length	A hydrophobic coating is applied to the surface of the balloon, the surface of the shaft and the entire inner lumen.	The hydrophobic coating covers the guidewire lumen, the outside of the distal tip, the surface of the WAVE balloon and the entire surface of the 2-lumen shaft up to 7.5cm ± 2.5cm before the strain relief.
Marker band #	2 (Tungsten Polymer marker)	2 (PT 90%, IR10%)
Balloon Material	Polyamide 12	Grilamid L25 (Polyamide 12)
Sterilization Method	EO	EO
Dimensions		
Catheter Working Length	90 cm and 150 cm	90 cm and 145 cm
Catheter Shaft Outer Diameter	distal shaft diameter: 0.94 mm proximal shaft diameter: 1.33 mm	1.27 mm
Balloon Length	20, 40, 60, 80, 120, 200 mm	20, 40, 85, 120, 150 mm
Balloon Diameter	1.5, 2.0, 2.5, 3.0, and 4.0 mm	2.0, 2.5, 3.0, 3.5, and 4.0 mm
No. of Inflations	1 (one) or more as needed	Minimum 2 (two) with the second one repositioned proximally by 3 mm
Inflation ramp and hold	N/A	Slowly inflate and hold for 120 seconds

Device description:	The WAVE product is constructed from a 2-lumen catheter shaft connected to a manifold located at the proximal end, and a fixed-length non-compliant balloon with an atraumatic tip located on the distal end of the shaft. The first lumen serves as a guidewire lumen (max. 0.014") that passes from the distal tip of the balloon through an inner member to a straight entry port (guidewire port) located on the manifold at the proximal end of the WAVE catheter. The second lumen serves as a balloon inflation lumen that extends from the balloon to a side leg port (inflation port) on the manifold. The balloon has two radiopaque marker bands indicating the nominal length of the balloon and facilitating balloon positioning. The manifold is bonded to the 2-lumen shaft via an UV-adhesive, and the transition covered by a strain relief for kink prevention. The WAVE catheter is provided with a hydrophobic coating, which facilitates insertion and handling of the product. To maintain the profile of the folded balloon during transportation and storage, the WAVE product is packaged together with a balloon protector. A packaging stylet ensures lumen viability of the balloon inner member and eases insertion of the WAVE catheter into the primary packaging. The hydrophobic coating covers the guidewire lumen, the outside of the distal tip, the surface of the WAVE balloon and the entire surface of the 2-lumen shaft up to 7.5cm ± 2.5cm before the strain relief. The WAVE PTA Balloon Catheter is based on a segmented balloon technology with n-balloon segments divided by n-1 waists. Each diameter has a dedicated design of the waists.
Indications for Use:	The WAVE PTA Balloon Catheter is indicated to dilate stenoses in femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
Fundamental Scientific Technology:	The WAVE PTA Balloon Catheter is based on a segmented balloon technology with n-balloon segments divided by n-1 waists. Each diameter has a dedicated design of the waists.

Summary of Non-Clinical Performance Data:

Non-Clinical verification and validation tests have been performed with regards to the intended use, the technical claims, the requirement specifications and the risk management results.

The WAVE PTA Balloon Catheter underwent the following performance testing:

- Visual Inspection and Dimensional Verification
- Simulated Use
- Balloon Rated Burst Pressure
- Balloon Fatigue
- Balloon Compliance Testing
- Inflation / Deflation Time
- Bond Strength
- Tip Pull
- Flexibility and Kink
- Torque Strength
- Radiopacity
- Coating Integrity
- Particulate Evaluation
- Guidewire Compatibility
- Corrosion Resistance
- Biocompatibility per ISO 10993-1
- Sterilization
- Shelf-Life
- Packaging Testing

Non-Clinical verification and validation test results demonstrate that the WAVE PTA Balloon Catheter meets acceptance criteria.

Therefore, the WAVE PTA Balloon Catheter is substantially equivalent to the primary currently marketed and predicate device (K102705).

Summary of Clinical Data:

Clinical studies were not needed to support substantial equivalence between subjects and predicate devices. Substantial equivalence was demonstrated with non-clinical performance tests. Therefore, the WAVE PTA Balloon Catheter did not require clinical data.

Substantial Equivalence Conclusion:

The WAVE PTA Balloon Catheter is substantially equivalent to the primary currently marketed and predicate device (K102705) in terms of design features, fundamental scientific technology, and indications for use. Additionally, substantial equivalence was demonstrated with non-clinical performance (verification and validation) tests, which complied with the requirements specified in FDA's Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters guidance and international and FDA-recognized consensus standards, ISO 10555, and ISO 14971. The results of these tests demonstrate that WAVE PTA Balloon Catheter met the acceptance criteria to demonstrate substantial equivalent to the predicate device.