



December 19, 2025

% Jennifer Houck
Principal Regulatory Affairs Specialist
Liva Nova Usa, Inc.
14401 W. 65th Way
Arvada, Colorado 80004

Re: K253616

Trade/Device Name: ProtekDilate Vascular Access Kit
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel dilator for percutaneous catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: November 17, 2025
Received: November 18, 2025

Dear Jennifer Houck:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

FINN E.
DONALDSON -S

Digitally signed by FINN
E. DONALDSON -S
Date: 2025.12.19
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Finn Donaldson
Acting 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

Indications for Use

510(k) Number (if known)
K253616

Device Name
ProtekDilate Vascular Access Kit

Indications for Use (Describe)

The ProtekDilate Vascular Access Kits are intended for single use by a trained physician to assist in vessel cannulation.

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
(in accordance with 21 CFR 807.92)

I. Applicant Information

Applicant:

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Contact Person:

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Principal Regulatory Affairs Specialist
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Date Prepared:

December 18th 2025

II. Subject Device Identification

Device Trade Name: ProtekDilate Vascular Access Kit

510(k) Number: K253616

Classification Name: Dilator, Vessel, For Percutaneous Catheterization

Regulation Number: 21 CFR 870.1310

Product Code: DRE

Classification: Class II

Classification Panel: Cardiovascular

III. Predicate Device

The ProtekDilate Vascular Access Kits are substantially equivalent to the following cleared predicate device. The subject device and predicate device have the same fundamental scientific technology and intended use:

Predicate Device		
ProtekDuo Venous Dilator Set	510(k) Number:	K162181
	Device Trade Name:	ProtekDuo Venous Dilator Set (14 Fr to 26 Fr)
	Classification Name:	Dilator, Vessel, for Percutaneous Catheterization
	Regulation Number:	21 CFR 870.1310
	Product Code:	DRE
	Classification:	Class II
	Classification Panel:	Cardiovascular
Reference Device		
MC3 Vascular Access Kit 21030	510(k) Number:	K182914
	Device Trade Name:	MC3 Vascular Access Kit 21030
	Classification Name:	Dilator, Vessel, for Percutaneous Catheterization
	Regulation Number:	21 CFR 870.1310
	Product Code:	DRE
	Classification:	Class II
	Classification Panel:	Cardiovascular

IV. Device Description

The subject device ProtekDilate Vascular Access Kits are intended for single use by a trained physician to assist in vessel cannulation. The subject device kits are comprised of eight (8) vascular dilators with diameters of 8/10, 14, 16, 18, 22, 26, 28, and 30 Fr. The dilators are designed to accept 0.035" and 0.038" guidewires and consists of hubs comprised of ABS. Additional kit components include a #11 scalpel, 18 GA Seldinger type echogenic introducer needle, 10 cc syringe, and two 0.035" or 0.038" guidewires. All kit components, including the 8/10 Fr dilator (8/10 Two Stage Dilator, K162389), are off-the-shelf with the exception of the 14-30 Fr dilators, which will be manufactured by Sorin Group Italia S.R.L..

The ProtekDilate Vascular Access Kits are sterile, non-pyrogenic devices for single use only, and are not to be re-sterilized by the user.

V. Indications for Use

The ProtekDilate Vascular Access Kits are intended for single use by a trained physician to assist in vessel cannulation.

VI. Comparison to the Predicate Device

The subject device (ProtekDilate Vascular Access Kits) is identical to the predicate (ProtekDuo Venous Dilator Set), with respect to device technology, principle of operation, sterilization method, and shelf-life. There were minor modifications which incorporated (1) addition of dilator sizes 8/10, 16, 28, and 30 Fr, (2) an increase in dilator durometer from 90A to 95A, (3) modifications made to the dilator hub material from PVC to ABS, and (4) an update to the dilator packaging from pouch to a tray configuration.

VII. Non-Clinical Performance Data

The Subject Device ProtekDilate Vascular Access Kits underwent Verification and Validation activities to address the modifications made since clearance of the Predicate Device ProtekDuo Venous Dilator Set (14 Fr to 26 Fr). These activities are outlined below:

- Deflection Testing
- Pull/Tensile Testing
- Sterilization
- Shelf Life
- Package Integrity
- Biocompatibility
 - Cytotoxicity
 - Hemocompatibility

The Subject Device ProtekDilate Vascular Access Kits met the acceptance criteria identified in the non-clinical performance testing and demonstrated the device is substantially equivalent to the predicate device.

VIII. Statement of Substantial Equivalence

Based on equivalent intended use and technological characteristics the ProtekDilate Vascular Access Kits can be deemed to be substantially equivalent to their predicate device (ProtekDuo Venous Dilator Set (14 Fr to 26 Fr), K162181) and reference device (MC3 Vascular Access Kit 21030, K182914).