May 5, 2022

Abbott Vascular
Jiyoung Dang
Associate Director Regulatory Affairs
3200 Lakeside Drive
Santa Clara, California 95054

Re: K221057
Trade/Device Name: Viatrac 14 Plus Peripheral Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: April 6, 2022
Received: April 11, 2022

Dear Jiyoung Dang:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221057

Device Name
Viatrac 14 Plus Peripheral Dilatation Catheter

Indications for Use *(Describe)*
The Viatrac 14 Plus Peripheral Dilatation Catheter is indicated to dilate stenosis in the peripheral vasculature (iliac, femoral, ilio-femoral, popliteal, infra-popliteal, renal arteries, and carotid arties) or for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon-expandable and self-expanding stents in the peripheral vasculature.

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

The 510(k) Summary is prepared in accordance with 21 CFR Part 807.92

Submitter's Name:	Abbott Vascular
Submitter's Address:	3200 Lakeside Drive Santa Clara, CA 95054
Telephone: **Fax:**	408-845-3000 408-845-3743
Contact Person:	Jiyoung M. Dang, Ph.D. Associate Director Regulatory Affairs
Date Prepared:	May 5, 2022
Device Trade Name:	Viatrac 14 Plus Peripheral Dilatation Catheter
Classification Name:	Percutaneous Catheter (21 CFR 870.1250)
Regulatory Class:	Class II
Product Code	LIT
Predicate Device:	K072798 Viatrac 14 Plus Peripheral Dilatation Catheter

Summary of Substantial Equivalence:

The subject device Viatrac 14 Plus Peripheral Dilatation Catheter is comprised of an inner member material that is produced using a similar resin material, due to a material source change, as compared to the predicate Viatrac 14 Plus Peripheral Dilatation Catheter. The change in resin material source does not alter the Viatrac 14 Plus Peripheral Dilatation Catheter's technological characteristic, device design, or manufacturing process. There is no change to the intended use or indication for use. Therefore, the subject device Viatrac 14 Plus Peripheral Dilatation Catheter can be concluded to be substantially equivalent to the predicate Viatrac 14 Plus Peripheral Dilatation Catheter.

Device Description:

The Viatrac 14 Plus Peripheral Dilatation Catheter has an integrated shaft system and a balloon near the distal tip. The shaft has a combination of the single lumen and dual lumen tubing. One lumen is used for the inflation of the balloon with a contrast medium. The second lumen in the distal shaft permits the use of a guidewire to facilitate the advancement of the catheter to and through the stenosis to be dilated.

The balloon has radiopaque marker(s) to aid in positioning the balloon in the stenosis and is designed to provide an expandable segment of known diameter and length at a specific pressure.

On the 135 cm catheter length, there are two proximal shaft markers (95 cm and 105 cm from the distal tip). On the 80 cm catheter length, there is a single proximal marker (55 cm from the distal tip). Both

indicate the relative position of the catheter to the end of a brachial, femoral, or renal guiding catheter. An additional marker is located at the guidewire exit notch and aids in locating the guidewire exit notch.

Intended Use:

The Viatrac 14 Plus Peripheral Dilatation Catheter is indicated to dilate stenosis in the peripheral vasculature (iliac, femoral, iliofemoral, popliteal, infra-popliteal, renal arteries, and carotid arteries) or for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon-expandable and self-expanding stents in the peripheral vasculature.

Technological Characteristics:

There have been no changes to the technological characteristics such as device design, performance properties, sterilization, and packaging. The difference in resin material source does not alter the device technological characteristics, therefore the subject device can be considered substantially equivalent to the predicate device.

Performance Data:

The substantial equivalence of the Viatrac 14 Plus Peripheral Dilatation Catheter has been demonstrated through:

- Biocompatibility assessment in accordance with ISO 10993 series of standards for biological evaluation of medical devices consisting of the following:
    - Cytotoxicity
    - Sensitization
    - Hemocompatibility (hemolysis, complement activation, thrombogenicity)
    - Pyrogenicity

- Functional testing consisting of:
    - Catheter bend integrity
    - Inner member lumen collapse
    - Catheter tensile integrity
    - Tip tensile

Conclusions:

The Viactrac 14 Plus Peripheral Dilataion Catheter has the same intended use and operating principle and technology as the predicate device. The only difference between the subject device and predicate device is a change in the resin material used in the inner member material. Biocompatibility and functional testing were performed. The results of these tests demonstrate that the subject device performs as intended and does not raise new questions of safety and effectiveness.