May 26, 2023

Summa Therapeutics, LLC
% Elena Jugo
Regulatory Consultant
Caraballo Consulting
11037 Bitternut Hickory Lane
Boynton Beach, Florida 33437

Re: K230263
Trade/Device Name: Finesse™ Injectable PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: May 2, 2023
Received: May 3, 2023

Dear Elena Jugo:

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,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.05.26 06:50:54 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230263

Device Name
Finesse Injectable™ PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The Finesse Injectable™ PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, 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.

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5 - 510(k) Summary

Date Summary Prepared: January 30, 2023

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Trade Name: Finesse Injectable™ PTA Balloon Dilatation Catheter

Regulation Number: 21 CFR 820.1250

Device Common or Classification Name: PTA Dilatation Catheter

Product Class: Class II

Product Panel: Cardiovascular

Product Code: LIT

Predicate Device: K150452, Finesse™ Injectable PTA Balloon Dilatation Catheter

Reference Predicate Device: K192318, Bard Peripheral Vascular, Inc. Ultraverse® 014 PTA Balloon Dilatation Catheter

5.1 Device Description

The Finesse Injectable™ PTA Balloon Dilatation Catheter is an over-the-wire balloon catheter for peripheral indications. The device features a semi-compliant balloon combined with a low-profile tip. The catheter is compatible with 0.014" (0.36 mm) guidewires and has a hydrophilic coating over its distal coaxial segment to facilitate advancement of the catheter to the treatment site.

The Finesse Injectable™ PTA Balloon Dilatation Catheter has a working length of 150 cm, and is available with balloon working lengths of 20, 40, 60, 100, and 225 mm. There are two radiopaque marker bands located within the balloon working length (one proximal and one distal). These radiopaque marker bands, in conjunction with fluoroscopy, aid in the placement of the catheter's balloon segment. There is one additional radiopaque marker located distal of the exit holes to aid in locating their position relative to a guiding sheath distal tip. The catheter construction consists of a catheter shaft with two independent lumens extending along its length. One lumen is for inflation and deflation of the angioplasty balloon. The other lumen is for placement of the guidewire and injection of fluids via the catheter's exit holes that are positioned proximal to the balloon. The proximal portion of the catheter comprises a hub that includes an extension tube with a female luer-lock port connected to a balloon inflation/deflation lumen, and a stopcock with female luer-lock port for fluid/contrast injection attached to the side port of a Touhy-Borst adapter that is in communication with the guidewire lumen.

5.2 Indications for Use

The Finesse Injectable™ PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

5.3 Technological Characteristics and Basis for Substantial Equivalence

The Finesse Injectable™ PTA Balloon Dilatation Catheter, subject of this 510(k) submission, is substantially equivalent in its intended use/indications for use, technology/principal of operation, biocompatibility of materials, sterilization method, packing, and performance to the predicate device, the ComboCath™ OTW PTA Dilation Catheter (Summa Therapeutics, LLC, Providence,

RI), and the reference predicate device, the Bard Peripheral Vascular, Inc. Ultraverse® 014 PTA Balloon Dilatation Catheter (C. R. Bard, Inc., Murray Hill, NJ).

A comparison of the technological characteristics of the subject device and the predicate devices is summarized in **Table 5.3.1**. All characteristics noted are the same as, or within the range, of the primary predicate device and/or the reference predicate device.

Table 5.3.1 - Comparison Between the Finesse Injectable™ PTA Balloon Dilatation Catheter and Predicate Devices

Parameter	**Subject Device Finesse Injectable™ PTA Balloon Dilatation Catheter**	**Primary Predicate Device ComboCath™ OTW PTA Dilatation Catheter 510(k) # K150452**	**Reference Predicate Device Ultraverse® 014 and 018 PTA Balloon Dilatation Catheters 510(k) # K192318**	**Equivalence Comparison**
Indications for Use	The Finesse Injectable™ PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.	The ComboCath™ OTW PTA Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.	Ultraverse® 014 and Ultraverse® 018 PTA Balloon Dilatation Catheters are recommended for use in percutaneous transluminal angioplasty (PTA) of the renal, popliteal, tibial, femoral, and peroneal arteries. These catheters are not for use in coronary arteries.	**Same as the Primary Predicate**
Product Code	LIT	LIT	LIT	**Same**
Regulation No.	21CFR 870.1250	21CFR 870.1250	21CFR 870.1250	**Same**
Classification	Class II	Class II	Class II	**Same**
Design	• Over-the-wire • Two lumen catheter shaft: 1 lumen for balloon inflation and 1 lumen for the guidewire and injection of fluids • Thermoplastic polymer balloon • Radiopaque markers	• Over-the-wire • Two lumen catheter shaft: 1 lumen for balloon inflation and 1 lumen for the guidewire and injection of fluids • Thermoplastic polymer balloon • Radiopaque markers	• Over-the-wire • Coaxial lumen • Radiopaque markers	**Same as Primary Predicate**
Shaft and Balloon Material	Thermoplastic	Thermoplastic	Information not available	**Same as Primary Predicate**

Table 5.3.1 - Comparison Between the Finesse Injectable™ PTA Balloon Dilatation Catheter and Predicate Devices

Parameter	Subject Device Finesse Injectable™ PTA Balloon Dilatation Catheter	Primary Predicate Device ComboCath™ OTW PTA Dilatation Catheter 510(k) # K150452	Reference Predicate Device Ultraverse® 014 and 018 PTA Balloon Dilatation Catheters 510(k) # K192318	Equivalence Comparison
Balloon Diameter	2.0, 2.5, 3.0, 3.5, 4.0 mm	2.5, 3.0, 3.5, 4.0 mm	1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0 mm	**Within the range of sizes of the Reference Predicate**
Balloon Length	20, 40, 60, 100, 225 mm	40 mm	20, 40, 60, 80, 100, 120, 150, 200, 220, 250, 300 mm	**Within the range of sizes of the Reference Predicate**
Working Length	150 cm	150 cm	75, 90, 100, 130, 150, and 200 cm	**Same**
Coating	Hydrophilic Coating	None	Hydrophilic Coating	**Same as the Reference Predicate**
Guidewire Compatibility	0.14 inches	0.14 inches	014": 0.14 inches 018": 0.14 or 0.18 inches	**Same**
Sheath Compatibility	5 Fr	5 Fr	014": 4 Fr, 5 Fr 018": 4 Fr, 5 Fr, 6 Fr	**Same**
Single Use Only	Yes	Yes	Yes	**Same**
Sterilization	E-beam Irradiation	E-beam Irradiation	Ethylene Oxide	**Same as the Primary Predicate**
Packaging	Catheter is packaged inside dispensing coil or packaging tray; Tyvek pouch; cardboard box	Catheter is packaged inside dispensing coil or packaging tray; Tyvek pouch; cardboard box	Information not available	**Same as the Primary Predicate**

5.4 Performance Data

Design verification and validation were performed to ensure that the Finesse Injectable™ PTA Balloon Dilatation Catheter meets its performance specifications and demonstrates substantial equivalence to the predicate devices. There are no known performance standards for this device. The following tests were conducted to demonstrate performance equivalence to the predicate device:

- Sterility Testing
- Package Integrity
- Crossing Profile
- Balloon Outer Diameter
- Tip/Lesion Entry Profile
- Tip ID
- Catheter Useable Length
- Injection Exit Hole Dimensions and Locations

- Marker Band Position
- Balloon Burst Strength
- Balloon Compliance
- Balloon Working Length
- Inflation/Deflation Time
- Balloon Fatigue
- Catheter Bond Tensile Strength
- Kink Resistance
- Balloon Preparation, Deployment, and Retraction
- Introducer Sheath Compatibility
- Torque Tolerance
- Radiopacity
- Infusion Rate
- Catheter Body Burst Pressure
- Guidewire Compatibility
- Coating Integrity
- Particulate Generation

Results from all tests were acceptable. The data demonstrate that the Finesse Injectable™ PTA Balloon Dilatation Catheter is substantially equivalent to the predicate devices.

5.5 Biocompatibility Testing

The Finesse Injectable™ PTA Balloon Dilatation Catheter was assessed for biocompatibility in accordance with ISO 10993-1, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process". The Finesse Injectable™ PTA Balloon Catheter has limited contact (≤ 24 hours), and as such, the following tests were performed to ensure it is biocompatible:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Hemocompatibility
    - Scanning Electron Microscopy
- Bacterial Endotoxin

The biocompatibility testing met all requirements.

5.6 Conclusion

Review of the verification and validation test data as well as comparison of the device classification, indications for use, operating principle, technological characteristics, sterility, and biocompatibility, demonstrate that the subject device, the Finesse Injectable™ PTA Balloon Dilatation Catheter, is substantially equivalent to the primary predicate device, the ComboCath™ OTW PTA Dilatation Catheter, K150452, cleared on August 13, 2015.