January 15, 2020

NexStep Medical
℅ Angela Mallery
Principal Product Development Strategist, Regulatory
NAMSA
400 Highway 169 South, Suite 500
Minneapolis, MN 55426

Re: K191275
Trade/Device Name: All'InCath 035M PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, KRA
Dated: December 11, 2019
Received: December 12, 2019

Dear Ms. Mallery:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191275

Device Name
The All'InCath 035M PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The All'InCath 035M PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
The All'InCath 035M is also intended to provide angiographic visualization of the vasculature when combined with the delivery of radiopaque contrast media.
This catheter is not for use in coronary arteries.

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

K191275

Submitter	NexStep Medical 7-9 Place Saint Bernard 21000 Dijon France
Contact Person	Angela Mallery 400 Highway 169 South Minneapolis, MN 55426 Phone: (763) 287-3830 amallery@namsa.com
Date Prepared	January 14, 2020
Trade Name	All'InCath 035M PTA Balloon Dilatation Catheter
Classification	Regulation Number: 21 CFR 870.1250 Regulation Name: Catheter, Angioplasty, Peripheral, Transluminal Common Name: PTA Balloon Dilatation Catheter Regulatory Class: Class II Product Code: LIT, KRA Product Panel: Cardiovascular
Device Description	The All'InCath 035M PTA Balloon Dilatation Catheter (All'InCath 035M) is a sterile single use dilatation balloon and contrast injection catheter. The All'InCath 035M is an over the wire (OTW) catheter compatible with 0.035" (0.89mm) guidewire. The proximal end of the catheter includes a three ports hub connected to the three lumens of the shaft: the port provided with a stopcock valve is used for angiographic contrast injection, the straight entry port allows access to the distal tip of the catheter for guidewire insertion, and the last port is used for balloon inflation/deflation. Contrast is injected into the vascular system through three holes in the contrast lumen proximal to the balloon and marked by a radiopaque marker. The balloon is mounted at the distal end of the catheter. The balloon has two radiopaque markers indicating the dilating section of the balloon and aid positioning the balloon relative to the lesion. The tip of the catheter is made of a soft radiopaque tubing.
Indication for Use	The All'InCath 035M PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

	The All'InCath 035M is also intended to provide angiographic visualization of the vasculature when combined with the delivery of radiopaque contrast media. This catheter is not for use in coronary arteries.
Technological Characteristics	Comparisons of the new and predicate devices show the technological characteristics such as product performance, design, and intended use are substantially equivalent to the currently marketed predicate devices.
Primary Predicate Device	K140351 Arrow GPSCath
Reference Device	K170635 AV Medical Technologies Ltd. Chameleon K113468 Biotronik, Inc. Passeo-35HP
Summary of Technological Characteristics of the New Device in Comparison to those of the Predicate evice	The information provided in this section demonstrates the All'InCath 035M is substantially equivalent to the Primary Predicate in terms of performance characteristics and materials. The All'InCath 035M is considered equivalent to the primary predicate. • The All'InCath 035M has an equivalent indication for use statement • The All'InCath 035M has the equivalent technological characteristics • The testing has demonstrated the differences between the All'InCath 035M and the predicate/reference devices do not raise different questions of safety and effectiveness The table shows the analysis that establishes how the All'InCath 035M is substantially equivalent.

Substantial Equivalence Executive Summary

Comparison Items	All'InCath 035M	Primary Predicate	Reference Devices	
		K140351 GPSCath	K170635 Chameleon	K113468[1] Passeo-35 HP
Intended Use	A percutaneous catheter is a device that is introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire for Percutaneous Transluminal Angioplasty in the peripheral vasculature and for the treatment of	A percutaneous catheter is a device that is introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire for Percutaneous Transluminal Angioplasty in the peripheral vasculature and for the treatment of	A percutaneous catheter is a device that is introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire for Percutaneous Transluminal Angioplasty in the peripheral vasculature and for the treatment of	A percutaneous catheter is a device that is introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire for Percutaneous Transluminal Angioplasty in the peripheral vasculature and for the treatment of

[1] K113468 was initially cleared as the Creagh Medical ELM PTA Catheter, it is a non-coated PTA device. Access GUIDID database lists this as being marketed under the Brand name Passeo-35

		obstructive lesions of native or synthetic arteriovenous dialysis fistulae	obstructive lesions of native or synthetic arteriovenous dialysis fistulae	obstructive lesions of native or synthetic arteriovenous dialysis fistulae	obstructive lesions of native or synthetic arteriovenous dialysis fistulae	
	Indications for Use	The All'InCath 035M PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The All'InCath is also intended to provide angiographic visualization of the vasculature when combined with the delivery of radiopaque contrast media. This catheter is not for use in coronary arteries	The Arrow GPSCath™ Balloon Dilatation Catheter (150cm) 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. This catheter is not for use in coronary arteries.	The Chameleon PTA Balloon Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The Chameleon enables the infusion of diagnostic or therapeutic fluids. This catheter is not for use in coronary arteries or cerebral vasculature.	The ELM PTA Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, and the renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary arteries.	
	Primary Product Code	LIT	LIT	LIT	LIT	
	Catheter Type	OTW	OTW	OTW	OTW	
	Balloon Material	Vestamid	Unknown	Unknown	Nylon/Pebax, controlled compliance	
	Device Coating(s)	No coating.	No coating	No coating	No coating	
	Useable Catheter Length	80-120 cm	80-150 cm	75 cm	40-75[2] cm	

[2] https://biotronik.cdn.mediamid.com/cdn_bio_doc/bio24718/20818/bio24718.pdf

Balloon Diameter	4.0-10.0 mm	3.0-12 mm	5.0-12 mm	3.0-12.0 mm
Balloon Length	20-80 mm	20-100 mm	40 mm	20-100 mm
Guidewire Compatibility	0.035”	0.035”	0.035”	0.035”
Nominal Pressure (atm)	6	8	12-14	12-14
RBP (atm)	14-18	16-24	14-25	18-27
Marker Bands Present	Yes	Yes	Yes	Yes
Can Infuse Contrast	Yes	Yes	Yes	No
Packaging	Pouch in Pressboard carton	Pouch in Pressboard carton	Pouch in Pressboard carton	Pouch in Pressboard carton
Sterilization	EO	EO	EO	EO

Intended Use

The general purpose and function of the devices are equivalent.

The devices are all intended to be introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire for Percutaneous Transluminal Angioplasty in the peripheral vasculature and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Indication for use

The subject device has an equivalent indication for use to that of the GPSCath and a similar indication to the reference devices.

Substantial Equivalence Conclusion

The All’InCath 035M is substantially equivalent to the predicate device and reference devices.

The devices have similar designs, however the exact specifications between the subject and primary predicate/reference devices differ in certain aspects. In each case where there was a difference, design verification testing was performed to demonstrate substantial equivalence.

In all cases, performance testing demonstrated the device performed as intended.

The devices are considered equivalent for the following reasons:

- The All’InCath 035M does not raise different questions of safety and effectiveness
- The All’InCath 035M has the equivalent indication for use statement as the predicate and reference devices
- The design of the All’InCath 035M and the predicate and reference devices are substantially equivalent with minor differences to the device dimensions, materials types, and performance

	• The testing has demonstrated the differences between the All'InCath 035M and the predicate/reference devices do not raise different questions of safety and effectiveness
Performance Data	*In vitro* performance tests, including dimensional verification, balloon rated burst pressure, balloon fatigue, balloon compliance, balloon inflation and deflation time, catheter bond strength, tip pull strength, trackability, and radiopacity and biocompatibility tests, such as cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemocompatibility (hemolysis, complement activation, and *in vivo* thromboresistance), and pyrogenicity were conducted. The test results met all acceptance criteria and ensure the design and construction are suitable for its intended use as recommended by the Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (FDA; September 8, 2010). A pre-clinical study was conducted to evaluate the acute safety and performance of the device during angiography and angioplasty procedures as compared to Biotronik-Passeo-35 PTA catheter and Boston Scientific Contra 4F angiography catheter in a porcine vascular model by assessing the angiographic appearance, ergonomics, total procedure time, amount of contrast, and vessel damage. The catheter has been evaluated in accordance with ISO 10993-1 and ISO 11135.
Conclusion	This information supports a determination of substantial equivalence between the All'InCath 035M PTA Balloon Dilatation Catheter and the predicate and reference devices described above.