April 29, 2021

Medcaptain Life Science Co., Ltd.
David Xia
Official Correspondent
601, Building C, Jinweiyuan Industrial Park,
Pingshan District
Shenzhen, Guangdong 518118
China

Re: K202619
Trade/Device Name: KardiFlex™ PTCA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: March 30, 2021
Received: April 1, 2021

Dear David Xia:

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: 2021.04.29 10:10:13 -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)*
K202619

Device Name
KardiFlex PTCA Balloon Dilatation Catheter

Indications for Use *(Describe)*
KardiFlex PTCA Balloon Dilatation Catheter is indicated for:
-balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.
-balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction.

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

KardiFlex™ PTCA Balloon Dilatation Catheter
21 CFR §870.5100(a)
Date prepared: April 29, 2021

This 510(k) Summary is submitted in accordance with 21 CFR 807.92(c).

I. Submitter/510(k) Holder

Submission:	Traditional 510(k) Premarket Notification
Submitter:	Medcaptain Life Science Co., Ltd
Address:	601, Building C, Jinweiyuan Industrial Park, Pingshan District, Shenzhen, Guangdong, CN 518118.
Contact:	David Xia
Telephone:	+86-755-28380626
Telefax:	+86-755-84517910
Email:	david.xia@medcaptain.com

II. Device information

Device Trade Name:	KardiFlex™ PTCA Balloon Dilatation Catheter
Device Common Name:	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Classification Name:	Catheter, transluminal coronary angioplasty, percutaneous
Classification Regulation:	21 CFR 870.5100(a)
Product Code:	LOX
Device Class:	Class II
Classification Panel:	Cardiovascular
510(k) Number:	K202619

III. Predicate Device

The KardiFlex™ PTCA Balloon Dilatation Catheter is substantially equivalent to the following device:
Predicate Device: Sapphire II Pro Coronary Dilatation Catheter (K163114, OrbusNeich Medical, Inc.) cleared on May 1, 2017.

The following reference devices are used in this submission:
Reference Device 1: Sapphire Coronary Dilatation Catheter (K103657, OrbusNeich

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Medical, Inc.) cleared on August 9, 2011.
Reference Device 2: Sapphire II PRO Balloon Dilatation Catheter (K180921, OrbusNeich Medical Trading, Inc.) cleared on June 28, 2018.
Reference Device 3: Selethru PTCA Balloon Dilatation Catheter (K182699, Kossel Medtech (Suzhou) Co., Ltd.) cleared on November 26, 2018.

IV. Device Description

The KardiFlex™ PTCA Balloon Dilatation Catheter is designed to allow rapid exchange of the catheter using a standard length of 0.014" guide wire. Balloon diameters range from 1.5mm to 4.0mm and lengths from 6mm to 30mm. The balloon material is made of compliant material and balloons have a rated burst pressure of 16 atmospheres. The compliant material allows high pressure dilatation while maintaining precise control of the balloon diameter and length.

The KardiFlex™ PTCA Balloon Dilatation Catheter is a sterile, single use and non-pyrogenic device. The balloon has one (for ∅1.5mm) or two (for ∅2.0-4.0mm) radiopaque platinum marker(s) to aid in positioning the balloon in the stenosis and is designed to provide an expandable segment of known diameter and length of a specific pressure. The dilatation catheter is coated with hydrophilic coating, which is activated when wet. The proximal shaft of the catheter is composed of a female luer connector (hub) bonded to a PTFE coated stainless steel tube (hypotube).

The KardiFlex™ PTCA Balloon Dilatation Catheter consists of 10 parts: hub, strain relief, hypotube, distal outer body, inner body, balloon, radiopaque platinum marker band, tip, balloon sheath and stylet.

V. Indications for Use

KardiFlex™ PTCA Balloon Dilatation Catheter is indicated for:
• balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.
• balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction.

VI. Comparison to Predicate Device

The subject device, KardiFlex™ PTCA Balloon Dilatation Catheter, and the predicate device, Sapphire II Pro Coronary Dilatation Catheter , are substantially equivalent in that these devices, at a high level, have the same technological characteristics: intended use, indications for use, operation principle and design (such as rapid exchange catheter design, hydrophilic coating applied in the distal section, semi-compliant balloon, 0.014inch guidewire compatibility, EO sterilization

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and single use), prescription use, target user, use environment, balloon diameter, etc.

The differences between the subject and the predicate devices include balloon length range, working length, rated burst pressure 16 atm (vs. 14atm.), etc., do not raise new or different questions for regarding safety or effectiveness. Testing requirements for the subject device are based on upon the *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (FDA; September 8, 2010).*

Similarities and differences in technologies characteristics are captured in the substantial equivalence comparison of the subject device, KardiFlex™ PTCA Balloon Dilatation Catheter, and the predicate device, Sapphire II Pro Coronary Dilatation Catheter, which are provided in Table 1.

Table 1: Substantial Equivalence

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Description	Sapphire II Pro Coronary Dilatation Catheter (Predicate Device)	Sapphire Coronary Dilatation Catheter (Reference Device 1)	Sapphire II PRO Balloon Dilatation Catheter (Reference Device 2)	Selethru PTCA Balloon Dilatation Catheter (Reference Device 3)	KardiFlex™ PTCA Balloon Dilatation Catheter (Subject device)	Comparison to predicate/reference device
510(k) Number	K163114	K103657	K180921	K182699	K202619	N/A
Regulation Number	21 CFR 870.5100(a)	21 CFR 870.5100(a)	21 CFR 870.5100(a)	21 CFR 870.5100	21 CFR 870.5100(a)	Identical
Classification Name	Catheter, transluminal coronary angioplasty, percutaneous	Catheter, transluminal coronary angioplasty, percutaneous	Catheter, transluminal coronary angioplasty, percutaneous	Catheter, transluminal coronary angioplasty, percutaneous	Catheter, transluminal coronary angioplasty, percutaneous	Identical
Product Code	LOX	LOX	LOX(primary) LIT(secondary)	LOX	LOX	Identical to predicate device
Device Class	Class II	Class II	Class II	Class II	Class II	Identical
Intended Use	Sapphire II Pro Coronary Dilatation Catheter is intended for use in percutaneous transluminal coronary angioplasty (PTCA) to treat patients with coronary disease.	Sapphire Coronary Dilatation Catheter is intended for use in percutaneous transluminal coronary angioplasty (PTCA) to treat patients with coronary disease.	Sappgire II Pro Balloon Dilatation Catheter is intended for use in percutaneous transluminal coronary angioplasty (PTCA) to treat patients with coronary disease.	The Selethru PTCA Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.	KardiFlex™ PTCA Balloon Dilatation Catheter is intended for use in percutaneous transluminal coronary angioplasty (PTCA) to treat patients with coronary disease.	Identical to predicate device
Indications for use	The Sapphire II PRO coronary dilatation catheter is indicated for:	The Sapphire coronary dilatation catheter is indicated for:	The Sapphire® II PRO balloon dilatation catheter	The Selethru PTCA Balloon Dilatation	KardiFlex™ PTCA Balloon Dilatation	Identical to predicate device

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	• balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion. • balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction.	• balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion. • balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction.	(1.5-4.0mm configuration) is indicated for: • balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion. • balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction.	Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.	Catheter is indicated for: • balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion. • balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction.	
Operation principle and design	Sapphire II PRO Coronary Dilatation Catheter is a percutaneous transluminal coronary angioplasty (PTCA) balloon catheter with a working length of 140cm. The proximal shaft is a PTFE coated stainless	Sapphire Coronary Dilatation Catheter is a percutaneous transluminal coronary angioplasty (PTCA) balloon catheter with a working length of 140cm. The proximal shaft	Sapphire II PRO Balloon Dilatation Catheter is a rapid exchange balloon catheter with a working length of 140cm design for both coronary and peripheral indications.	The Selethru PTCA Balloon Dilatation Catheter is a rapid exchange (RX) PTCA Balloon Catheter, sterile, single use, intravascular medical device with a	KardiFlex™ PTCA Balloon Dilatation Catheter is a rapid exchange balloon catheter with a working length of 142.5cm design. The proximal	Substantially equivalent Differences do not raise new or different questions regarding safety or effectiveness.

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	steel hypotube. Hydrophilic lubricious coatings are applied to the distal section. The semi-compliant balloons can be inflated by injection dilute contrast media solution through the trailing hub of the catheter. Two radiopaque platinum marker bands are located within the balloon segment (only one centrally located marker band for 1.5 configurations). The catheter is compatible with 5F or larger guiding catheters. The internal lumen of the catheter accepts a standard 0.014inch PTCA guidewire. The proximal part of the guidewire enters the catheter tip and advances coaxially out the catheter proximal port, thereby allowing both coaxial guidance and rapid exchange of catheters with s single standard length	is a polymer coated stainless steel hypotube. Hydrophilic lubricious coatings are applied to the distal section. The semi-compliant balloons can be inflated by injection dilute contrast media solution through the trailing hub of the catheter. Two radiopaque platinum marker bands are located within the balloon segment (only one centrally located marker band for 1.5 configurations). The catheter is compatible with 5F or larger guiding catheters. The internal lumen of the catheter accepts a standard 0.014inch PTCA guidewire. The proximal part of the guidewire enters the	The proximal shaft is a PTFE coated stainless steel hypotube. Hydrophilic lubricious coatings are applied to the distal section. Semi-compliant balloons can be inflated by injection dilute contrast media solution through the trailing hub of the catheter Two radiopaque platinum marker bands are located within the balloon segment (only one centrally located marker band for 1.0-1.5 configurations). The catheter is compatible with 4F or larger sheaths or 5F or larger guiding catheters. The internal lumen of the catheter accepts a standard	working length of 142cm. The proximal shaft is PTFE coated stainless steel tube, which allows for exceptional pushability and a smooth transition to the distal shaft, which is composed of an outer tube, an inner tube, and a balloon. A hydrophilic coating is applied to the distal section. The proximal shaft of the catheter has two markers sections that aid in gauging dilatation catheter position relative to the guiding catheter tip). The distal shaft of the catheter has an integrated shaft system. The shaft has a combination of single lumen and dual	shaft is a PTFE coated stainless steel hypotube. Hydrophilic coatings are applied to the distal section. The semi-compliant balloons can be inflated by injection of dilute contrast media solution through the hub of the catheter. Two radiopaque platinum marker bands are located within the balloon segment (only one centrally located marker band for 1.5 configurations). The catheter is compatible with 5F or larger guiding catheters. The internal lumen of the catheter accepts a standard 0.014inch	

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	guidewire. Two marked sections are located on the hypotube shaft to indicate catheter position. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements.	catheter tip and advances coaxially out the catheter proximal port, thereby allowing both coaxial guidance and rapid exchange of catheters with s single standard length guidewire. Two marked sections are located on the hypotube shaft to indicate catheter position. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements.	0.014inch guidewire. The proximal part of the guidewire enters the catheter tip and advances coaxially out the catheter proximal port, thereby allowing both coaxial guidance and rapid exchange of catheters with s single standard length guidewire. Two marked sections are located on the hypotube shaft to indicate catheter position. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements.	lumen tubing. One lumen is used for inflation of the balloon with contrast medium. The other lumen in the distal shaft permits the use of a guidewire to facilitate advancement of the catheter. The guidewire enters the catheter tip and advances coaxially out the distal RX port. Two marker bands are located within the balloon segment. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements.	PTCA guidewire. The proximal part of the guidewire enters the catheter tip and advances coaxially out the catheter proximal port, thereby allowing both coaxial guidance and rapid exchange of catheters with s single standard length guidewire. Two marked sections are located on the hypotube shaft to indicate catheter position. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements.	
Prescription/ Over-the-Counter	Prescription	Prescription	Prescription	Prescription	Prescription	Identical
Target User	Intended for use by physicians	Intended for use by	Intended for use by	Intended for use by	Intended for use by	Identical

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		physicians	physicians	physicians	physicians	
Access/ Anatomical site:	Inserted percutaneously into the arterial circulation or bypass graft stenosis	Inserted percutaneously into the arterial circulation or bypass graft stenosis	Inserted percutaneously into the arterial circulation or bypass graft stenosis	Inserted percutaneously into the arterial circulation or bypass graft stenosis	Inserted percutaneously into the arterial circulation or bypass graft stenosis	Identical
Use environment:	Hospitals	Hospitals	Hospitals	Hospitals	Hospitals	Identical
Materials:	/	/	/	/	/	/
Balloon material	Pebax	Pebax	Pebax	/	Pebax	Identical
Hypotube	PTFE coated stainless steel	PTFE coated stainless steel	PTFE coated stainless steel	PTFE coated stainless steel	PTFE coated stainless steel	Identical
Marker bands	Platinum	Platinum	Platinum	Platinum	Platinum Alloys	Identical
Performance:	/	/	/		/	/
Dimensional verification	Balloon diameter: 1.5-4.0mm	Balloon diameter: 1.5-4.0mm	Balloon diameter: 1.5-4.0mm;	Balloon diameter: 1.5-4.0mm;	Balloon diameter: 1.5-4.0mm	Identical
	Balloon length: 10-30mm	Balloon length: 10-30mm	Balloon length: 5-30mm	Balloon length: 10-30mm	Balloon length: 6-30mm	Identical to Reference device 2 Differences do not raise new or different questions regarding safety or effectiveness.
	Working length: 140cm	Working length: 140cm	Working length: 140cm	Working length: 142cm	Working length: 142.5cm	Difference Differences do not

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						raise new or different questions regarding safety or effectiveness.
Balloon rated burst pressure	14atm	14atm	14atm	16atm	16atm	Identical to Reference device 3
Shaft burst	No such information	No such information	Pass test	No such information	Pass test	Identical to Reference device 2
Balloon fatigue	Pass test	Pass test	Pass test	Pass test	Pass test	Identical
Balloon compliance	Pass test	Pass test	Pass test	Pass test	Pass test	Identical
Balloon inflation and deflation time	Pass test	Pass test	Pass test	Pass test	Pass test	Identical
Catheter bond strength	Pass test	Pass test	Pass test	Pass test	Pass test	Identical
Tip pull test	Pass test	Pass test	Pass test	Pass test	Pass test	Identical
Flexibility and kinking	Pass test	Pass test	Pass test	Pass test	Pass test	Identical
Torque strength	Pass test	Pass test	Pass test	Pass test	Pass test	Identical
Radiopacity	Pass test	Pass test	Pass test	Pass test	Pass test	Identical
Coating integrity	Pass test	Pass test	Pass test	Pass test	Pass test	Identical
Particulate evaluation	Pass test	Pass test	Pass test	Pass test	Pass test	Identical
Visual inspection	No such information	No such information	Pass test	No such information	Pass test	Identical to Reference device 2

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Balloon preparation, deployment, and retraction	Pass test	Pass test	Pass test	No such information	Pass test	Identical
Energy type:	N.A	N.A	N.A	N.A	N.A	Identical
Biocompatibility:	ISO 10993	ISO 10993	ISO 10993	ISO 10993	ISO 10993	Identical
Sterilization:	Sterilized with ethylene oxide gas. Non-pyrogenic.	Sterilized with ethylene oxide gas. Non-pyrogenic.	Sterilized with ethylene oxide gas. Non-pyrogenic.	Sterility	Sterilized with ethylene oxide gas. Non-pyrogenic.	Identical
Single Use:	Single use	Single use	Single use	Single use	Single use	Identical
Shelf Life:	2 years	2 years	2 years	No such information	2 years	Identical

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VII. Performance Data

The subject device, KardiFlex™ PTCA Balloon Dilatation Catheter, was subjected to the following applicable testing to assure reliable design and performance under the specified testing parameters and ensure that 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)*:

Biocompatibility Testing:
Per ISO 10993-1: 2018 and FDA guidance, the following tests were performed to ensure the biocompatibility of the subject device.

- In vitro cytotoxicity, per ISO 10993-5: 2009
- Intracutaneous reactivity, per ISO 10993-10: 2010
- Skin sensitization, per ISO 10993-10: 2010
- Acute systemic toxicity, per ISO 10993-11: 2017
- Hemocompatibility (Hemolysis, Coagulation, Platelet count or leukocyte count, In Vivo Thromboresistance and Complement), per ISO 10993-4: 2017
- Material mediated pyrogenicity, per ISO 10993-11: 2017 and USP General Chapter <151>

Bench Testing (Zero Time and Accelerated Aged):

- Tip Configuration, per ISO 10555-1: 2013.
- Surface, per ISO 10555-1: 2013.
- Dimentional Verification, per ISO 10555-1: 2013, ISO 10555-4: 2013 and FDA guidance.
- Corrosion Resistance, per ISO 10555-1: 2013.
- Radio-detectability of Balloon Position, per ISO 10555-1: 2013, ISO 10555-4: 2013 and FDA guidance.
- Freedom from Leakage, per ISO 10555-1: 2013 and product characteristics.
- Hub, per ISO 10555-1: 2013.
- Balloon Rated Burst Pressure, per ISO 10555-4: 2013 and FDA guidance.
- Balloon Failure Mode, per ISO 10555-4: 2013.
- Balloon Fatigue, per ISO 10555-4: 2013 and FDA guidance.
- Diameter at Nominal Pressure, per ISO 10555-4: 2013.
- Balloon Compliance, per ISO 10555-4: 2013 and FDA guidance.
- Inflation Time, per FDA guidance.
- Deflation Time, per ISO 10555-4: 2013 and FDA guidance.
- Catheter Bond Strength, per ISO 10555-1: 2013 and FDA guidance.
- Entry Tip Crossing Profile.
- Balloon Preparation, Deployment and Retraction, per FDA guidance.

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- Tip Pull Test, per FDA guidance.
- Flexibility and Kink Test, per FDA guidance.
- Torque Strength, per FDA guidance.
- Coating Integrity, per FDA guidance.
- Particulate Evaluation, per FDA guidance, EN ISO 8536-4: 2020, USP <788>.
- Shaft Loose Part.
- Package Labeling, per ISO 10555-1: 2013, ISO 10555-4: 2013 and FDA guidance.
- Shelf Life, per FDA guidance.
- Package Seal Verification, per ISO 11607-1: 2019 and ISO 11607-2: 2019.
- Shipping and Handling, per ISTA 3A: 2018.
- Chemical performance, per ISO 8536-4: 2019.
- EtO Sterilization, per ISO 10993-7: 2008 and FDA guidance.
- Sterility, per ISO 11135: 2014 and FDA guidance.
- Bacterial Endotoxin, per ANSI/AAMI ST72: 2011.

VIII. Conclusion

The results of these tests confirm that the KardiFlex™ PTCA Balloon Dilatation Catheter meets the design input requirements based on the intended use and support the conclusion that this device does not raise new questions of safety and/or effectiveness and is substantially equivalent to the predicate device, Sapphire II Pro Coronary Dilatation Catheter (K163114, OrbusNeich Medical, Inc.).