May 6, 2021

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

Re: K202578
Trade/Device Name: KardiFlex™ NC Coronary Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: September 3, 2020
Received: September 8, 2020

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 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)*
K202578

Device Name
KardiFlex NC Coronary Dilatation Catheter

Indications for Use *(Describe)*
KardiFlex NC Coronary 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.
• in-stent restenosis.
• post-delivery expansion of balloon expandable coronary stents.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

MEDCAPTAIN LIFE SCIENCE CO., LTD.
601 Building C, Jinweiyuan Industrial Park, Pingshan District,
Shenzhen, Guangdong, CN 518118.
Tel.: +86-755-28380626 Email: disposable@medcaptain.com
Fax.: +86-755-84517910 Website: www.medcaptain.com

510(k) Summary

KardiFlex™ NC Coronary Dilatation Catheter
21 CFR §870.5100(a)
Date prepared: May 1, 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™ NC Coronary 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:	K202578

III. Predicate Device

The KardiFlex™ NC Coronary Dilatation Catheter is substantially equivalent to the following devices:
Predicate device: Sapphire NC Plus Coronary Dilatation Catheter (K192344, OrbusNeich Medical Trading, Inc.) cleared on September 19, 2019.

Reference device 1: Sapphire NC Coronary Dilatation Catheter (K103808,

MEDCAPTAIN LIFE SCIENCE CO., LTD.
601 Building C, Jinweiyuan Industrial Park, Pingshan District,
Shenzhen, Guangdong, CN 518118.
Tel.: +86-755-28380626 Email: disposable@medcaptain.com
Fax.: +86-755-84517910 Website: www.medcaptain.com

OrbusNeich Medical, Inc.) cleared on September 1, 2011.
And, reference device 2: RX NC Takeru PTCA Balloon Dilatation Catheter (K170941, Kaneka Corporation) were used in this submission.

IV. Device Description

The KardiFlex™ NC Coronary 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 5.0mm and lengths from 6mm to 30mm. The balloon material is made of a minimally Nylon material and balloons have a rated burst pressure of 22 atmospheres. The minimally material allows high pressure dilatation while maintaining precise control of the balloon diameter and length.

The KardiFlex™ NC Coronary Dilatation Catheter is a sterile, single use and non-pyrogenic device. The balloon has one (for ∅1.5mm) or two (for ∅2.0-5.0mm) 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™ NC Coronary 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™ NC Coronary 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.
- in-stent restenosis.
- post-delivery expansion of balloon expandable coronary stents.

VI. Comparison to Predicate Device

The subject device, KardiFlex™ NC Coronary Dilatation Catheter, and the predicate device, Sapphire NC Plus Coronary Dilatation Catheter, are substantially equivalent in that these devices, at a high level, have same technological element: intended use, indications for use, operation principle and design (such as rapid exchange catheter

MEDCAPTAIN LIFE SCIENCE CO., LTD.
601 Building C, Jinweiyuan Industrial Park, Pingshan District,
Shenzhen, Guangdong, CN 518118.
Tel.: +86-755-28380626 Email: disposable@medcaptain.com
Fax.: +86-755-84517910 Website: www.medcaptain.com

design, hydrophilic coating applied in the distal section, non-compliant balloon, 0.014inch guidewire compatibility, EO sterilization and single use), prescription use, target user, use environment, main materials, nominal pressure, etc.

The technological differences between the subject and the predicate device include balloon diameter range, balloon length range, working length, rated burst pressure. 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™ NC Coronary Dilatation Catheter, and the predicate device, Sapphire NC Plus Coronary Dilatation Catheter, which are provided in Table 1.

Table 1: Substantial Equivalence

Description	Sapphire NC Plus Coronary Dilatation Catheter (Predicate Device)	Sapphire NC Coronary Dilatation Catheter (Reference Device 1)	RX NC Takeru (Reference Device 2)	KardiFlex™ NC Coronary Dilatation Catheter (Subject device)	Comparison to predicate/reference device
510(k) Number	K192344	K103808	K170941	K202578	N/A
Regulation Number	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	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter	Catheter, transluminal coronary angioplasty, percutaneous	Identical
Product Code	LOX	LOX	LOX	LOX	Identical
Device Class	Class II	Class II	Class II	Class II	Identical
Intended Use	Sapphire NC Plus Coronary Dilatation Catheter is intended for use in percutaneous transluminal coronary angioplasty (PTCA) to treat patients with coronary disease.	Sapphire NC Coronary Dilatation Catheter is intended for use in percutaneous transluminal coronary angioplasty (PTCA) to treat patients with coronary disease.	RX NC Takeru Coronary Dilatation Catheter is intended for use in percutaneous transluminal coronary angioplasty (PTCA) to treat patients with coronary disease.	KardiFlex™ NC Coronary Dilatation Catheter is intended for use in percutaneous transluminal coronary angioplasty (PTCA) to treat patients with coronary disease.	Identical
Indications for use	Sapphire NC Plus	Sapphire NC Coronary	The RX NC Takeru	KardiFlex™ NC	Identical to

MEDCAPTAIN LIFE SCIENCE CO., LTD.
601 Building C, Jinweiyuan Industrial Park, Pingshan District,
Shenzhen, Guangdong, CN 518118.
Tel.: +86-755-28380626 Email: disposable@medcaptain.com
Fax.: +86-755-84517910 Website: www.medcaptain.com

	Coronary 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. •in-stent restenosis •post-delivery expansion of balloon expandable coronary stents.	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. •in-stent restenosis •post-delivery expansion of balloon expandable coronary stents.	PTCA Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion in coronary artery or bypass graft stenosis for the purpose of myocardial perfusion. This product is also indicated for the post-delivery expansion of balloon expandable stents	Coronary 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. •in-stent restenosis •post-delivery expansion of balloon expandable coronary stents.	predicate device
Operation principle and design	Sapphire NC Plus Coronary Dilatation Catheteris a percutaneous transluminal coronary angioplasty (PTCA) balloon catheter with a working length of 140cm.The proximal shaft is a polymer coated stainless steel hypotube. Lubricious coatings are applied to the distal section. The	Sapphire NC Coronary Dilatation Catheter is a percutaneous transluminal coronary angioplasty (PTCA) balloon catheter with a working length of 140cm. The proximal shaft is a polymer coated stainless steel hypotube. Lubricious coatings are applied to the distal section. The non-compliant balloons	RX NC Takeru PTCA Balloon Dilatation Catheter is a percutaneous transluminal coronary angioplasty (PTCA) balloon catheter with a working length of 145cm. RX NC Takeru is a rapid exchange type of balloon dilatation catheter, which consists of a distal tube, guidewire transition	KardiFlex™ NC Coronary Dilatation Catheter is a percutaneous transluminal coronary angioplasty (PTCA) balloon catheter with a working length of 142.5cm design. The proximal shaft is a PTFE coated stainless steel hypotube. Hydrophilic coatings are applied to the	Substantially equivalent Differences do not raise new or different questions regarding safety or effectiveness.

MEDCAPTAIN LIFE SCIENCE CO., LTD.
601 Building C, Jinweiyuan Industrial Park, Pingshan District,
Shenzhen, Guangdong, CN 518118.
Tel.: +86-755-28380626 Email: disposable@medcaptain.com
Fax.: +86-755-84517910 Website: www.medcaptain.com

	non-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. 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 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	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. 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 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.	tube, balloon, radiopaque markers, mid tube, proximal tube, core wire, hub, and strain relief. A balloon is attached to the distal end of the catheter, and it can be inflated and deflated using the inflation device connected to the hub at the proximal end. RX NC Takeru has a guidewire lumen at the distal end of the catheter through which a guidewire can be inserted, and also an opening along the guidewire transition tube to the guidewire port for the exit of a guidewire. The maximum compatible diameter of a guidewire is 0.014inches. Guiding catheters with a diameter of 5 or 6Fr have been deemed to be compatible with the RX NC Tekeru.	distal section. The non-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 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	

MEDCAPTAIN LIFE SCIENCE CO., LTD.
601 Building C, Jinweiyuan Industrial Park, Pingshan District,
Shenzhen, Guangdong, CN 518118.
Tel.: +86-755-28380626 Email: disposable@medcaptain.com
Fax.: +86-755-84517910 Website: www.medcaptain.com

	measurements.			incorporate a lumen for distal dye injections or distal pressure measurements.	
Prescription/ Over-the-Counter	Prescription	Prescription	Prescription	Prescription	Identical
Target User	Intended for use by physicians	Intended for use by physicians	Intended for use by physicians	Intended for use by physicians	Identical
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	Identical to predicate device
Use environment:	Hospitals	Hospitals	/	Hospitals	Identical to predicate device
Materials:	/	/	/	/	/
Balloon material	Nylon	Nylon	/	Nylon	Substantially equivalent Differences do not raise new or different questions regarding safety or effectiveness.
Hypotube	Polymer coated stainless steel	Polymer coated stainless steel	/	Polymer (PTFE) coated stainless steel	
Marker bands	Platinum	Platinum	/	Platinum Alloys	
Performance:	/	/	/	/	/
Dimension	Balloon diameter: 2.0-5.0mm	Balloon diameter: 2.0-4.0mm	Balloon diameter: 2.0-5.0mm	Balloon diameter: 1.5-5.0mm	Difference Differences do not raise new or different questions regarding safety or effectiveness.
	Balloon length: 8-18mm	Balloon length: 8-18mm	Balloon length: 6-30mm	Balloon length: 6-30mm	Identical to reference device 2
	Working length:	Working length: 140cm	Working length: 145cm	Working length:	Difference

MEDCAPTAIN LIFE SCIENCE CO., LTD.
601 Building C, Jinweiyuan Industrial Park, Pingshan District,
Shenzhen, Guangdong, CN 518118.
Tel.: +86-755-28380626 Email: disposable@medcaptain.com
Fax.: +86-755-84517910 Website: www.medcaptain.com

	140cm			142.5cm	Differences do not raise new or different questions regarding safety or effectiveness.
Balloon rated burst pressure	22atm (2.0-4.0) 20atm (4.5-5.0)	22atm (2.0-4.0)	20atm	22atm	Difference Differences do not raise new or different questions regarding safety or effectiveness.
Nominal pressure	12atm	12atm	12atm	12atm	Identical
Balloon fatigue	Pass test	Pass test	Pass test	Pass test	Identical
Balloon compliance	Pass test, non-compliance	Pass test, non-compliance	Pass test, non-compliance	Pass test, non-compliance	Identical
Balloon inflation and deflation time	Pass test	Pass test	Pass test	Pass test	Identical
Catheter bond strength	Pass test	Pass test	Pass test	Pass test	Identical
Tip pull test	Pass test	Pass test	Pass test	Pass test	Identical
Particulate evaluation	Pass test	Pass test	Pass test	Pass test	Identical
Visual inspection	Pass test	Pass test	Pass test	Pass test	Identical
Balloon preparation, deployment, and retraction	Pass test	Pass test	Pass test	Pass test	Identical
Balloon rated burst pressure (in stent)	Pass test	Pass test	Pass test	Pass test	Identical
Balloon fatigue (in s tent)	Pass test	Pass test	Pass test	Pass test	Identical
Flexibility and kinki ng	/	Pass test	Pass test	Pass test	Identical
Torque strength	/	Pass test	Pass test	Pass test	Identical
Radiopacity	/	Pass test	Pass test	Pass test	Identical
Coating integrity	/	Pass test	Pass test	Pass test	Identical

MEDCAPTAIN LIFE SCIENCE CO., LTD.
601 Building C, Jinweiyuan Industrial Park, Pingshan District,
Shenzhen, Guangdong, CN 518118.
Tel.: +86-755-28380626 Email: disposable@medcaptain.com
Fax.: +86-755-84517910 Website: www.medcaptain.com

Energy type:	N.A	N.A	N.A	N.A	Identical
Biocompatibility:	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.	Sterilized with ethylene oxide gas. Non-pyrogenic.	Identical
Single Use:	Single use	Single use	Single use	Single use	Identical
Shelf Life:	2 years	2 years	/	2 years	Identical to predicate device

VII. Performance Data

The subject device, KardiFlex™ NC Coronary 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):
Per ISO 10555-1: 2013, ISO 10555-4: 2013, FDA guidance "*Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (FDA; September 8, 2010)*", etc., the following tests were performed for bench testing:

- 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.

MEDCAPTAIN LIFE SCIENCE CO., LTD.
601 Building C, Jinweiyuan Industrial Park, Pingshan District,
Shenzhen, Guangdong, CN 518118.
Tel.: +86-755-28380626 Email: disposable@medcaptain.com
Fax.: +86-755-84517910 Website: www.medcaptain.com

- 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.
- Rated Burst Pressure (in stent), per FDA guidance.
- Balloon Fatigue (In stent), per FDA guidance.
- 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™ NC Coronary 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 devices, Sapphire NC Plus Coronary Dilatation Catheter (K192344, OrbusNeich Medical Trading Inc.).