April 6, 2023

Vaibhav Rajal
Hexacath
Official Correspondent for Hexacath
MDI Consultants Inc
55 Northern Blvd
Great Neck, New York 11021

Re: K222023
Trade/Device Name: RayFlow
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: Class II
Product Code: KRA,DQO
Dated: March 7, 2023
Received: March 7, 2023

Dear Vaibhav Rajal:

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,

Samuel G. Raben -S

for Lydia Glaw
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)*
K222023

Device Name
RayFlow

Indications for Use *(Describe)*
The RayFlow catheter is intended to be used in adults (patients aged 22 years and older) for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the coronary vasculature.
The RayFlow is not intended to be used in the neurovasculature

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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HEXACATH

510(k) SUMMARY

The assigned 510(k) number is K222023

1. Submitter's Identification:

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Date Summary Prepared: April 5, 2023

2. Name of the Device:

Trade Name: Rayflow

FDA Product Codes, Common Name and Regulation Number:

FDA Product Code	Common Name	Regulation Number
DQO	Catheter, Intravascular, Diagnostic	870.1200
DQY	Catheter, Percutaneous	870.1250
KRA	Catheter, Continuous Flush	870.1210

3. Information for the 510(k) Cleared Device (Predicate Device):

Primary Predicate Device

510(k) number	Predicate device	Regulation Number	Regulation Name	Product Code
K180959	Phenom 27 Catheter	870.1200	Percutaneous Catheter	DQY, KRA

Reference Predicate Device

510(k) number	Predicate device	Regulation Number	Regulation Name	Product Code
K170544	Langston Dual Lumen Catheter	870.1200	Diagnostic Intravascular Catheter	DQO

4. Device Description:

The RAYFLOW infusion catheter is a rapid exchange (RX) double lumen catheter with a series of holes and a radiopaque marker on its distal part.

The outer lumen along the entire length of the catheter is used to inject fluids (saline, medication or contrast media) through the holes. The inner RX lumen is dedicated to the passage of a 0.014” guidewire facilitating the progression of the RAYFLOW catheter through the arteries.

Four holes are located between the outer lumen and the surface of the catheter, allowing infusion of fluids into the blood resulting in a homogeneous mixing. Two holes located between the outer and inner lumen of the RAYFLOW catheter allow the measurement of the injected solution temperature by a specific pressure/temperature guidewire (Abbott PressureWire™ X Guidewire) at the moment the solution enters the artery.

The hub is standard sized and compatible with any automated pump injector used for the continuous infusion of saline/liquid at room temperature.

The RAYFLOW is provided sterile, sterilized with ethylene oxide. This device is for a single use only and packed in individual unit. A mandrel is inserted into the inner lumen to protect the integrity of the device.

5. Indications for Use:

The RayFlow catheter is intended to be used in adults (patients aged 22 years and older) for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the coronary vasculature.

The RayFlow is not intended to be used in the neurovasculature.

6. Comparison to the 510(k) Cleared Devices (Predicate Devices):

Table of Comparison to Legally Marketed Device and Discussion of Similarities and Differences:

Subject and predicate devices are used for the delivery of diagnostic or therapeutic agents into the vascular system. The proposed subject device RayFlow has been compared to Phenom

(K180959) and Langston (K170544) catheters as predicate devices for substantial equivalence. A table comparing the devices is provided as follows:

Item	1.Subject Device RayFlow	2.Primary predicate device Phenom 27 Catheter (K180959)	3.Reference predicate device Langston Dual Lumen Catheter (K170544)	Identified similarities or differences	
				1 vs 2	1 vs 3
General Comparison					
Indications for Use	The RayFlow catheter is intended to be used in adults (patients aged 22 years and older) for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the coronary vasculature. The RayFlow is not intended to be used in the neurovasculature.	Phenom Catheters are intended for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the neuro, peripheral, and coronary vasculatures.	The Langston dual lumen catheter is indicated for delivery of contrast medium in angiographic studies and for simultaneous pressure measurement from two sites. This type of pressure measurement is useful in determining transvalvular, intravascular, and intraventricular pressure gradients.	Both devices have the same Indications for use except that RayFlow is only used in the coronary vasculature. Differences identified (1) See below	Both devices allow delivery of contrast medium into the vascular system. Differences identified (1) See below
Device Description	The RayFlow infusion catheter is a rapid exchange (RX) double lumen catheter with a series of holes and a radiopaque marker on its distal part. The hub is standard sized and compatible with any automated pump injector used for the continuous infusion of saline/liquid at room temperature	The Phenom 27 Catheters are variable stiffness, single lumen catheters designed to access small, tortuous vasculature. They are available in a variety of lengths, stiffness and inner and outer diameters. The outer surface of the catheter is coated to aid in navigation in the vessel. The catheter also incorporates a liner to facilitate movement of introduction devices passing through its lumen. The distal tip has radiopaque marker(s) to aid visualization and positioning under fluoroscopy.	The Langston dual lumen catheter consists of a coaxial tube (outer lumen) mounted over a braided catheter shaft (inner lumen) and an extension line with a 3-way stopcock. The extension line with stopcock connects to the outer lumen. The outer lumen, inner lumen, and extension line are joined by an over molded manifold. The manifold also includes a luer that connects to the inner lumen. The manifold is printed with the Langston catheter length, French size, maximum guidewire diameter, and product logo (“Langston”). The Langston dual lumen catheter tip terminates in either a pigtail or multipurpose tip configuration	Both catheters are coated and have a radiopaque marker at the distal end to allow good visibility of the product during the procedure. Differences identified (2) See below	Both catheters are dual lumen catheters. Differences identified (2) See below
Use	Single Use	Single Use	Single Use	Both are single use devices.	Both are single use devices.
Sterilization	Ethylene oxide	Ethylene oxide	Ethylene oxide	Both devices are sterilized using ethylene oxide gas.	Both devices are sterilized using ethylene oxide gas.
Technological comparison: Summary of Pre-Clinical Bench Testing					
Dimensional The purpose is	Length: 140 cm Proximal outer	Length: 75 to 160 cm Proximal outer	Length: 100 to 125 cm	Differences identified	Differences identified

to verify that all visual and dimensional requirements will meet the specified attributes.	diameter: 2.01F (0.67mm) Proximal inner diameter: 0.019 inches (0.49mm) Distal outer diameter: 2.5F (0.84mm) Distal inner diameter: 0.028 inches (0.71mm)	diameter: 3.1F (1.02mm) Proximal inner diameter: 0.027 inches (0.69mm) Distal outer diameter: 2.8F (0.91mm) Distal inner diameter: 0.027 inches (0.69mm)	Outer lumen diameter: 6F or 7F Inner lumen diameter: 4F or 5F	(3) See below	(3) See below
Component dimension compatibility The purpose is to verify that the catheter can track through a guiding catheter and over a guide wire.	Guiding catheter with an ID ≥ 0.079" (≥ 5Fr) Guide wire that is 0.014" in diameter Pressure/ temperature guide wire that is 0.014" in diameter	Guiding catheter with an ID ≥ 0.0445" (≥ 3,39Fr) Guide wire that is ≤ 0.025" in diameter	Guide wire that is ≤ 0.038" (0.965 mm) in diameter	Differences identified (4) See below	Differences identified (4) See below
Accessibility/ Tractability Test Ability of the system to advance through the vessel to the target site using the recommended accessories.	The RayFlow catheter is able to advance through a coronary anatomical model.	The Phenom catheter is able to reach specific region of a tortuous model.	The Langston design has been verified through Tortuosity in Simulated Anatomy test. The results of the verification tests met the specified acceptance criteria and did not raise new safety or performance issues.	Both devices were able to move freely (advancement without blockage) through an anatomical model. See 510(k) Summary K180959 for primary predicate device See TR 20-014 for Subject device	Both devices were able to move freely (advancement without blockage) through an anatomical model. See 510(k) Summary K170544 for reference predicate device See TR 20-014 for Subject device
Freedom from leakage (at hub) No liquid leakage detected per ISO 10555-1:2013 Annex C. Method, equipment and conditions as prescribed in standard.	RayFlow catheter showed no sign of leakage.	Phenom catheter showed no sign of leakage.	The Langston design has been verified through Liquid Leakage Under Pressure test. The results of the verification tests met the specified acceptance criteria and did not raise new safety or performance issues.	Both devices are conform to ISO 10555-1. See 510(k) Summary K180959 for primary predicate device See TR 20-014 for Subject device	Both devices are conform to ISO 10555-1. See 510(k) Summary K170544 for reference predicate device See TR 20-014 for Subject device
Flow Rate This test method is to verify the compliance to catheter standard ISO 10555-1:2013. Conditions, method and equipment as prescribed in the standard.	Presence of: Outer lumen side holes: 4 Inner lumen side holes : 2 Instruction for use: - Maximum flowrate: ≤ 25 ml/min (350 PSI)	Not applicable to the Phenom catheter. I Instruction for use: For a catheter of 135cm (useful length): **At 100% of physiologic serum** - 100 psi: 126 mL/min - 300 psi: 186 mL/min **At 100% of contrast media (76%)** - 100 psi: 12 mL/min - 300 psi: 36 mL/min **At 50/50 of contrast media (76%) and physiologic serum**	Presence of: Outer lumen side holes: 8 Inner lumen side holes : 2 or 5 Maximum flowrate: from 13 ml/sec to 1 ml/sec Maximum pressure rating: from 1000 PSI to 1200 PSI	Differences identified (5) See below	Differences identified (5) See below

		- 100 psi: 72 mL/min - 300 psi: 102 mL/min			
Tensile Strength The junctions should meet the tensile strength requirement per ISO 10555-1:2013 Annex B. Method, equipment and conditions as prescribed in standard	Minimal breaking strength: - 3N for ≥ 0,55 < 0,75 diameters - 5N for ≥ 0,75 < 1,15 diameters	Phenom catheter is conform to ISO 10555-1:2013.	The Langston design has been verified through Tensile Force test. The results of the verification tests met the specified acceptance criteria and did not raise new safety or performance issues.	Both devices are conform to ISO 10555-1. See 510(k) Summary K180959 for primary predicate device See TR 20-014 for Subject device	Both devices are conform to ISO 10555-1. See 510(k) Summary K170544 for reference predicate device See TR 20-014 for Subject device
Material Verification The purpose is to verify that all materials are as specified in raw material, final assembly, subassembly specifications and vendor certifications	Hub: Polycarbonate /PEBAX Strain relief: PEBAX Hypotube: Stainless steel + PTFE coating Middle tubing: Polyamide Inner tubing: PEBAX / LLDPE / Polyethylene Sleeve: PEBAX Marker: Platinum/Iridium Soft tip: PEBAX Coating: Hydrophilic coating	Hub: Polyamide Strain relief: Thermoplastic elastomer Shaft: Stainless Steel Reinforcement + PTFE composite polymeric catheter NA NA NA Marker: Platinum/Iridium Alloy NA Coating: Polymeric hydrophilic coating	Not enough information regarding materials used for the Langston	Differences identified (6) See below	Differences identified (6) See below

Discussion of Similarities and Differences between the proposed subject device and both the primary and reference predicate devices.

(1) Indications for use

1 vs 2 : Proposed Subject Device and Primary Predicate Device:
Primary predicate device Phenom is indicated for use in the neuro and peripheral vasculatures. This indication is not claimed for the subject device RayFlow so, effectiveness of the subject device RayFlow is not called into question as no additional use have been added in comparison to the indications for use of the primary predicate device Phenom.

1 vs 3: Proposed Subject Device and Reference Predicate Device:
Reference predicate device Langston is indicated for simultaneous pressure measurement from two sites. This indication is not claimed for the subject device RayFlow so, effectiveness of the subject device RayFlow is not called into question.
Reference predicate device Langston is used to account for the use of a temperature / pressure guidewire with the subject device RayFlow.

(2) Device description

1 vs 2: Proposed Subject Device and Primary Predicate Device:
Primary predicate device Phenom has only 1 lumen.
This difference does not raise new performance issues as well as safety issues. Effectiveness of the subject device RayFlow is not called into question as it has been tested according to ISO 10555-1 and ISO 25539-2.

1 vs 3: Proposed Subject Device and Reference Predicate Device:
Reference predicate device Langston is composed of an extension line with a 3-way stopcock while the subject device RayFlow does not. But this is a recommended equipment listed in the instruction for use of the subject device RayFlow.
This difference does not raise new performance issues as well as safety issues. Effectiveness of the subject device RayFlow is not called into question as it has been tested according to ISO 10555-1 and ISO 25539-2.

(3) Dimensional

1 vs 2: Proposed Subject Device and Primary Predicate Device:
The length of the subject device RayFlow catheter fits in the range proposed for the primary predicate device Phenom.
The distal inner diameter of the primary predicate device Phenom is equivalent to the distal inner diameter of the subject device RayFlow.
The outer diameters of the primary predicate device Phenom are larger than the outer diameters of the subject device RayFlow.
This difference does not raise new performance issues (accessories compatibility) as well as safety issues (less risk of damaging the vessels with a thinner catheter). Effectiveness of the subject device RayFlow is not called into question as it has been tested according to ISO 10555-1.

1 vs 3: Proposed Subject Device and Reference Predicate Device:
The diameters of the reference predicate device Langston are larger than the diameters of the subject device RayFlow.
These differences do not raise new performance issues (accessories compatibility) as well as safety issues (less risk of damaging the vessels with a thinner catheter). Effectiveness of the subject device RayFlow is not called into question as it has been tested according to ISO 10555-1.

(4) Component dimension compatibility

1 vs 2: Proposed Subject Device and Primary Predicate Device:
Accessory devices to be used are similar but have different dimensions. Nevertheless, for each device, the compatibility with accessories has been verified.
These differences do not raise new performance issues as well as safety issues. Effectiveness of the subject device RayFlow is not called into question as it has been tested according to ISO 25539-2.

1 vs 3: Proposed Subject Device and Reference Predicate Device:

Accessory devices to be used are similar but have different dimensions. Nevertheless, for each device, the compatibility with accessories has been verified.
These differences do not raise new performance issues as well as safety issues. Effectiveness of the subject device RayFlow is not called into question as it has been tested according to ISO 25539-2.

(5) Flowrate

1 vs 2: Proposed Subject Device and Primary Predicate Device:
There is no side holes on the primary predicate device Phenom. The infusion holes at distal end of the subject device RayFlow allow complete mixing compared to a regular infusion catheter and do not raise performance or safety issues (validated through pre-clinical and clinical data).
Infusion pressures recommended in both instructions for use are similar.
Flowrates indicated for the subject device RayFlow are different but they are validated through clinical data. The subject device RayFlow does not raise new safety or performance issues.
Effectiveness of the subject device RayFlow is not called into question as it has been tested according to ISO 10555-1.
1 vs 3: Proposed Subject Device and Reference Predicate Device:
The reference predicate device Langston has more side holes on its outer lumen (8 vs 4).
The reference predicate device Langston allows higher flowrate / pressure.
Flowrates indicated for the subject device RayFlow are different but they are validated through clinical data. The subject device RayFlow does not raise new safety or performance issues.
Effectiveness of the subject device RayFlow is not called into question as it has been tested according to ISO 10555-1.

(6) Material verification

1 vs 2: Proposed Subject Device and Primary Predicate Device:
Some materials used in the design of the subject device RayFlow are not used in the primary predicate device Phenom.
Nevertheless, biocompatibility testing was performed on the subject device RayFlow following ISO 10993-1 in order to validate the biological safety of the product:

- Chemical characterization (ISO 10993-18)
- Cytotoxicity (ISO 10993-5)
- Irritation or intracutaneous reactivity (ISO 10993-10)
- Acute systemic toxicity (ISO 10993-11)
- Hemocompatibility (ISO 10993-4)
- Pyrogenicity (ISO 10993-11)

1 vs 3: Proposed Subject Device and Reference Predicate Device:
The reference predicate device Langston has no marker band.
The radiopacity of the subject device RayFlow marker band will be validated during pre-clinical testing following ISO 10555-1.
Biological tests according to ISO 10993-1 were done on the reference predicate device Langston in order to validate the biological safety of the product.

Same biocompatibility testing were performed for the subject device RayFlow following ISO 10993-1 in order to validate the biological safety of the product:

- Chemical characterization (ISO 10993-18)
- Cytotoxicity (ISO 10993-5)
- Irritation or intracutaneous reactivity (ISO 10993-10)
- Acute systemic toxicity (ISO 10993-11)
- Hemocompatibility (ISO 10993-4)
- Pyrogenicity (ISO 10993-11)

Summary of substantial equivalence

Subject device RayFlow vs Primary predicate device Phenom

Technological characteristics of the subject device RayFlow are substantially equivalent with regard to the basic design and function of the predicate device.
Outer diameters as well as recommended flowrates differ from the primary predicate device Phenom. However, these differences do not alter the intended use of the subject RayFlow, and do not raise any new questions regarding safety or effectiveness when compared to the primary predicate device Phenom.
Based on the non-clinical testing already performed following catheter standard and on the risk management activities, the subject RayFlow is as safe and as effective than the predicate device Phenom.
In conclusion, the subject device RayFlow is substantially equivalent to the primary predicate device Phenom.

Subject device RayFlow vs Reference predicate device Langston

Technological characteristics of the subject device RayFlow are substantially equivalent with regard to the basic design and function of the reference predicate device Langston.
Outer diameters as well as recommended flowrates differ from the reference predicate device Langston. However, these differences do not alter the intended use of the subject device RayFlow, and do not raise any new questions regarding safety or effectiveness when compared to the reference predicate device Langston.
Based on the non-clinical testing already performed following catheter standard and on the risk management activities, the subject device RayFlow is as safe and as effective than the reference predicate device Langston.
In conclusion, the subject device RayFlow is substantially equivalent to the reference predicate device Langston.

Conclusions:

Based on the aforementioned comparison chart and the supporting performance testing, risk analysis and risk assessment the proposed subject device RayFlow is substantial equivalent to both the primary predicate device Phenom and the reference predicate device Langston.

7. Performance Testing:

The following Bench Performance testing were conducted on the proposed subject device to determine the performance and efficacy of the device:

Standards:

- ISO 10555-1: 2013 / AMD1:2017 Intravascular catheters - Sterile and single-use catheters — Part 1: general requirements
- ISO 25539-2: 2020 Cardiovascular implants - Endovascular devices — Part 2: vascular stents

Test performed:

- Dimensional
- Flowrate
- Power injection
- Freedom from leakage
- Tensile strength
- Flexibility/kink
- Torsional bond strength
- Simulated use
- Radiopacity
- Corrosion
- Acute particulate evaluation

8. Biocompatibility Testing:

Biocompatibility tests have been performed on the RAYFLOW following ISO 10993 standards. According to ISO 10993-1:2018, the RAYFLOW is classified as externally communicating medical devices in limited contact (<24h) with circulating blood. Based on ISO 10993-1 classification following biocompatibility testing have been conducted on the proposed subject device

- Analysis of raw materials and analysis of leachables/extractables,
- Cytotoxicity,
- Sensitization,
- Irritation or intracutaneous reactivity,
- Material mediated pyrogenicity
- Hemocompatibility

All biocompatibility tests have been conducted in compliance with the corresponding ISO 10993 standards. Devices tested were not cytotoxic, not sensitizing, did not induce intracutaneous reactivity, were found non-pyrogenic, not acutely toxic and hemocompatible. The completion of these tests is in favor of the biological safety of the RAYFLOW

9. Sterilization

Ethylene Oxide gas sterilization, using ISO 11135:2014. An Overkill approach method with a total of three consecutive experiments producing total inactivation of biological indicators (with a population of not less than 106) was performed to confirm the minimum exposure time.

The proposed subject device RayFlow is labeled “PYROGEN FREE".

10. Risk Analysis

The proposed subject RayFlow Device complies with the ISO 14971:2019 Medical devices - Application of risk management to medical devices” test standard. The testing ensures that the proposed subject device Rayflow was shown to be substantially equivalent to the predicate device.

11. Product Shelf Life

An accelerated aging testing as per ASTM F1980-16 was conducted to support the claim of 3 years shelf life for the proposed subject Rayflow device.

12. Packaging Materials / Packaging Validation

The RayFlow packaging is composed of:

- A plastic hoop dispenser ensuring a mechanical protection of the device;
- A Tyvek pouch ensuring a sterile barrier (primary packaging). It contains the device inside the hoop dispenser;
- A cardboard box containing the sterile unit and the the instructions for use (secondary packaging).

The RayFlow is placed inside the primary packaging which is sealed. The primary packaging is labeled and placed inside the secondary packaging with the Instruction for Use. The secondary packaging is closed and the same label as for the primary packaging is affixed on it.

Sealing process has been validated according to ISO 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems and ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.

13. Clinical Study Literature:

Literature articles based on the clinical studies conducted on the proposed subject device have been included to support the performance of the subject device.

14. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

In-vitro tests were conducted to validate the design and verify the performances and safety of the RayFlow. The following matrix summarizes all the in-vitro tests performed.

Standard	Title of the standard
Risk management	
ISO 14971:2019	Medical devices - Application of risk management to medical devices
Usability	
EN 62366-1:2015 / AMD1:2020*	Medical devices – application for usability engineering to medical devices
*The text of the International Standard IEC 62366-1:2015/A1:2020 was approved as a European Standard without any modification.	
Product standard	
ISO 80369-7:2016	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
ISO 10555-1: 2013 / AMD1:2017	Intravascular catheters - Sterile and single-use catheters — Part 1: general requirements
ISO 25539-2: 2020	Cardiovascular implants - Endovascular devices — Part 2: vascular stents
ASTM F640−20	Standard Test Methods for Determining Radiopacity for Medical Use
Biocompatibility	
ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 10993-4:2017	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood
ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993-7:2008 / AMD1:2019	Biological evaluation of medical devices — Part 7: Ethylene Oxide sterilization residuals
ISO 10993-10:2010	Biological evaluation of medical devices — part 10: tests for irritation and skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
ISO 10993-17:2002	Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances
ISO 10993-18:2020	Biological evaluation of medical devices — Part 18: Chemical characterization of materials
Packaging	
ISO 11607-1:2019	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging system
ISO 11607-2:2019	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
ASTM F1929-15	Standard Test Method For Detecting Seal Leaks In Porous Medical Packaging By Dye Penetration
ASTM F88/F88M-15	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems
Labeling	
ISO 15223-1:2021	Medical Devices – Symbols to be used with medical devices labels,

Standard	Title of the standard
	labeling and information to be supplied — Part 1: General requirements
Sampling	
ISO 2859-1:1999 / AMD1:2011	Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
Accelerated aging	
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical devices
Sterilization	
ISO 11135:2014 / AMD1:2018	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11737-1:2018	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
ISO 11737-2:2019	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 11138-1:2017	Sterilization of health care products — Biological indicators —Part 1: General requirements
European Pharmacopoeia, 8th edition (2019/07) Chapter 2.6.1*	Sterility test
*The current USP General Chapter <71> “Sterility test” is harmonized with the European Pharmacopeia.	
European Pharmacopoeia, 9th edition (2019/07) Chapter 2.6.14*	Bacterial endotoxin
*The current USP General Chapter <85> “Bacterial Endotoxin Test” is harmonized with the European Pharmacopeia.	

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that the proposed subject RayFlow device tested met all relevant requirements of the aforementioned tests.

Conclusions:

The design, characteristics, and performance of the proposed subject Rayflow device substantiates that the device is working as intended and there are no new issues of safety or effectiveness. The proposed subject Rayflow device is substantially equivalent to both its primary predicate device and the reference predicate device.