July 11, 2024

Rapid Medical Ltd.
Ina Gutman
RA/QA Director
Carmel Building, P.O. Box 337
Yokneam, 2069205
Israel

Re: K233791
Trade/Device Name: Drivewire 24 Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: June 10, 2024
Received: June 10, 2024

Dear Ina Gutman:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233791

Device Name
Drivewire 24 Guidewire

Indications for Use *(Describe)*
The Drivewire 24 Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The Drivewire 24 Guidewire is intended to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in the 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
K233791

Submission Sponsor

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Date Prepared

July 09, 2024

Device Identification

Trade/Proprietary Name: Drivewire 24 Guidewire
Common/Usual Name: Drivewire 24 Guidewire
Classification Name: Guide, Wire, Catheter, Neurovasculature
Regulation Number: 21 CFR 870.1330
Product Codes: MOF, DQX
Device Class: II
Classification Panel: Neurology, Cardiovascular

Legally Marketed Predicate Device

Predicate Device: Aristotle 24 Guidewire (K192783)

Indications for Use Statement

The Drivewire 24 Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The Drivewire 24 Guidewire is intended to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in the coronary arteries.

Device Description

The Drivewire 24 Guidewire is a 0.024" diameter steerable guidewire with a deflectable tip to aid in accessing vasculature. The guidewire is supplied sterile (ETO sterilization) and is for single use only.

The Drivewire 24 Guidewire is comprised of a stainless steel hypotube that is cut along its length to provide flexibility and tip deflection ability through control of the handle, an inner Nitinol braided flexible coil, an inner core wire, and a handle. The inner core wire runs inside the hypotube from the distal end to the handle. The distal end of the inner core wire is flattened, looped around and joined to the tip of the distal section of the hypotube, forming a deflectable tip. The hypotube is marked with fluoro-safe markers to provide visual clues to the user to initiate fluoroscopy guided insertion.

In order to actuate the tip deflection in two directions, the Drivewire 24 Guidewire handle contains a tube assembly section. The handle is assembled to the proximal end of the core wire and controls the movement of the distal tip by pulling/pushing the inner moveable core wire, allowing the bending of the distal tip in two directions. The handle assembly has neutral landmarks to identify the location where the tip is straight.

The Drivewire 24 Guidewire has a hydrophilic coating on its distal segment in order to reduce the friction of the guidewire while navigating.

The Drivewire 24 Guidewire is provided with a torque accessory to facilitate use of the guidewire and is not intended to have patient contact.

Comparison of Technological Characteristics

The table below compares the indications for use, principles of operation, technological characteristics, and materials of the Drivewire 24 Guidewire with that of the predicate device (the Aristotle 24 Guidewire). The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The differences in technological characteristics of the Drivewire 24 Guidewire do not raise any new questions of safety or effectiveness.

	Drivewire 24 Guidewire (Subject device)	**Aristotle 24 Guidewire (Predicate device)**	**Columbus Guidewire (Reference Device)**
510(k) Number	K233791	K192783	K200374
Regulation	21 CFR 870.1330	21 CFR 870.1330	21 CFR 870.1330
Product Code	MOF, DQX	MOF, DQX	MOF, DQX

	Drivewire 24 Guidewire (Subject device)	Aristotle 24 Guidewire (Predicate device)	Columbus Guidewire (Reference Device)
Indications for Use	The Drivewire 24 Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The Drivewire 24 Guidewire is intended to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in the coronary arteries.	The Aristotle 24 Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.	The Columbus Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The Columbus Guidewire is intended to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.
Anatomical Location	General intravascular use, including the neuro and peripheral vasculature but not coronary arteries.	General intravascular use, including the neuro and peripheral vasculature but not coronary arteries.	General intravascular use, including the neuro and peripheral vasculature but not coronary arteries.
Overall Length	204 cm	200 cm	200 cm
Distal Diameter	0.024”	0.024”	0.014”
Core Wire Material	Nitinol	Stainless Steel	Nitinol
Proximal Section Material	Stainless Steel	Nitinol	Stainless Steel
Radiopaque Coil	Nitinol and Nitinol DFT 30% tantalum	Platinum wire marker coil	Nitinol and Nitinol DFT 30% tantalum/ DFT 40% Platinum
Distal Tip Type and Length	Steerable 1.6 cm	Shapeable 35 cm	Steerable 2 cm (Columbus LR GWPP4464) 1.5 cm (Columbus LR GWPP4463)
Hydrophilic Coating	42 cm	46 cm	No coating
Sterilization	Sterile	Sterile	Sterile
Sterilization Method	Ethylene oxide	Ethylene oxide	Ethylene oxide
Single Use	Yes	Yes	Yes

Packaging	Placed into a Dispenser hoop, Tyvek pouch, and Carton box	Placed into a Dispenser hoop, Tyvek pouch, and Carton box	Placed into a Dispenser hoop, Tyvek pouch, and Carton box

Non-Clinical Testing

In order to demonstrate safety and performance of the subject device and to support substantial equivalence to the predicate device, Rapid Medical Ltd. completed a number of non-clinical performance tests.

Bench Tests

The subject device passed all non-clinical performance bench testing in accordance with internal requirements, national standards and international standards as shown in the table below to support substantial equivalence of the device.

Performance Bench Testing		
Test	**Test Method Summary**	**Results**
Visual and Dimensional Verification	The overall guidewire length, diameter, and bend diameter, and coating length were measured. A visual inspection confirmed there was no damage to device.	Dimensional and visual inspection results meet acceptance criteria.
Tip Flexibility	The force required to flex the distal tip was measured using a loading cell.	Tip flexibility was shown to be comparable to the predicate device.
Tip Deflection Force	The force that the guidewire tip applies on the vessel wall was measured using a loading cell.	The force applied by the tip is equal to or less than the predicate device's.
Simulated Use - Delivery and Retrieval Force	Forces for delivery and retrieval of the guidewire through simulated use vascular model were measured.	The delivery and retrieval forces were less than the predicate device's.
Simulated Use - Performance and Compatibility	Guidewire performance and compatibility were assessed in a simulated use model.	All devices met acceptance criteria in demonstrating the intended use of the guidewire in challenging simulated use conditions.
Usability Evaluation	Physicians evaluated the guidewire in clinically relevant simulated use models.	The device met the acceptance criteria.

Performance Bench Testing		
Test	**Test Method Summary**	**Results**
Torqueability	The ability of the guidewire to translate torque from the proximal end to the distal end was measured.	All devices met acceptance criteria in having the required initial rotation to the point when the tip starts to respond be equivalent to or less than the predicate device.
Kink Resistance	Kink resistance was tested along the guidewire by wrapping the device around mandrels of smaller radii until failure.	All devices met acceptance criteria for kink resistance which represent clinical use scenarios.
Fracture Test	The guidewire was wound around a cylinder and examined for fractures or other damage.	All devices met the acceptance criteria of having no fractures, loosening, or failures.
Flexing Test	The distal portion of the guidewire was subjected to repeated bending and examined for damage.	All devices met the acceptance criteria of having no fractures, loosening, or failures.
Tensile Force	The tensile strength of the guidewire joints was measured.	All joints met peak tensile force acceptance criteria established by delivery and retrieval force testing.
Tip Mechanism Durability	In a simulated use model, the tip deflection mechanism was cycled to assess durability.	All devices met acceptance criteria of withstanding a predetermined number of handle actuations.
Torque Strength	With the distal tip constrained, the number of turns to failure was measured.	All devices met the acceptance criteria of having the number of turns to failure be no less than a predetermined value.
Torquer Performance	The torque device was tested for performance (functional, tensile and torque) with the guidewire.	All devices met acceptance criteria of having no damage to the handle or shaft, and equivalent or higher tensile force and measured torque force at slipping to predicate device.
Particulate	Particulates were measured under simulated use conditions.	All devices have particulates equivalent or less than the predicate device.
Lubricity	A pinch test using a pushability test system was performed on the device through cycles to measure the friction properties of the hydrophilic coating	All devices met the acceptance criteria of having a maximal force and an average force comparable to the predicate device.

Coating integrity	Visual inspection of hydrophilic coating following simulated use was performed.	All devices met the acceptance criteria of having no coating separation after simulated use testing.
Radiopacity	Images were evaluated during the animal study.	All devices were visible under fluoroscopy.
Corrosion	The device was tested according to Annex B of ISO 11070: 2014(E).	The test sample did not have evidence of corrosion.

Biocompatibility

Biocompatibility testing was completed for the Drivewire 24 Guidewire in accordance with ISO 10993 and consisted of the following tests:

Test	Test Description	Results
Cytotoxicity	Cytotoxicity study using ISO Elution Method	The test article extract showed no evidence of causing cell lysis or toxicity. The test met the requirements as the grade was less than a grade 2 (mild reactivity).
Irritation (Intracutaneous Reactivity)	ISO Intracutaneous Irritation Study using extracts	The test article met the requirements, with no differences between each test article extract's overall mean score and the corresponding control extract's mean score.
Sensitization	ISO Guinea Pig Maximization Sensitization Test	Test articles showed no evidence of causing delayed dermal contact sensitization and were not considered sensitizers.
Hemocompatibility – Hemolysis	ASTM Hemolysis Study – Extract and Direct Contact	The test articles, both in direct and indirect contact with blood, were non-hemolytic.
Hemocompatibility – Complement Activation	SC5b-9 Complement Activation Assay	The test article was not considered a potential activator of the complement system.
Pyrogenicity	USP Rabbit Pyrogen Study, Material Mediated	The total rise of rabbit temperatures during the observation period was within acceptable USP limits. The test article was considered nonpyrogenic.
Acute Systemic Toxicity	ISO Acute Systemic Toxicity in Mice	There was no mortality or evidence of systemic toxicity from extracts injected into mice.
In Vivo Thrombogenicity	In vivo thrombogenicity in a porcine model	There was no evidence of thrombus formation.

All tests confirmed that the Drivewire 24 Guidewire met biological safety requirements per the ISO 10993 standard.

Animal Study

Rapid Medical Ltd. completed an acute, Good Laboratory Practices (GLP) study in domestic swine to support the substantial equivalence of the Drivewire 24 Guidewire to the predicate device. Devices were navigated to the left and right renal arteries and allowed dwell for 10 minutes, removed, examined for thrombus, scored, and photographed; this procedure was repeated three times for a total dwell time of 30 minutes. Activated clotting times were maintained within clinically relevant limits (250-350 seconds) throughout the procedure. After termination, the renal arteries, medulla, and capsule were examined. There was no evidence of thrombus on devices, in renal arteries or in downstream organs (kidney). Therefore, the study results support the thromboresistance of the Drivewire 24 Guidewire as substantially equivalent to that of the Aristotle 24 Guidewire.

Sterilization and Shelf Life

The device and its accessories underwent sterilization validation studies in accordance with ISO 11135: 2014/AC: 2014 ("Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices") requirements to demonstrate that the Ethylene Oxide (EtO) sterilization process will reliably sterilize the product loads to a sterility assurance level (SAL) of 10^{-6} or less, according to the overkill half cycle approach and relevant standards.

The Drivewire 24 Guidewire device and package met all shelf life and package integrity test acceptance criteria supporting a shelf-life of one (1) year.

Clinical Testing

No clinical studies were conducted, as substantial equivalence of the Drivewire 24 Guidewire to the predicate device is established through the non-clinical bench, biocompatibility, and animal testing.

Conclusion of Substantial Equivalence

The Drivewire 24 Guidewire has the same intended use and similar indications for use and technological characteristics compared to the predicate Aristotle 24 Guidewire. The differences do not raise new or different questions regarding the safety and effectiveness of the device. The non-clinical bench, biocompatibility, shelf-life, and animal testing with passing results discussed above further support the substantial equivalence of the Drivewire 24 Guidewire to the predicate device.