July 17, 2026

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

Re: K254006
Trade/Device Name: Drivewire 35 Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: June 15, 2026
Received: June 15, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, PhD
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)*
K254006

Device Name
Drivewire 35 Guidewire

Indications for Use *(Describe)*
The Drivewire 35 Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The Drivewire 35 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.**

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.***

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# 510(k) Summary K254006

## Submission Sponsor

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## Contacts:

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## Date Prepared

June 10, 2026

## Device Identification

**Trade/Proprietary Name:** Drivewire 35 Guidewire
**Common/Usual Name:** Drivewire 35 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: Drivewire 24 Guidewire (K233791)

## Reference Device

Reference Device: Aristotle Colossus Guidewire (K222437)

## Indications for Use Statement

The Drivewire 35 Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The Drivewire 35 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 35 guidewire is a 0.035” diameter steerable guidewire with a deflectable tip to aid in accessing vasculature. The guidewire is supplied sterile (ethylene oxide (ETO) sterilization) and is for single use only.

The Drivewire 35 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, a proximal hypotube, 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.

In order to actuate the tip deflection in two directions, the Drivewire 35 Guidewire handle contains a stainless-steel tube and a plastic parts 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 movable 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 35 Guidewire has a hydrophilic coating on its distal segment in order to reduce the friction of the guidewire while navigating.

The Drivewire 35 Guidewire is provided with a “Torquer” 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 35 Guidewire with that of the predicate device (the Drivewire 24 Guidewire). The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The differences in the technological characteristics of the Drivewire 35 Guidewire do not raise any new questions of safety or effectiveness.

| | Drivewire 35 Guidewire (Subject device) | Drivewire 24 Guidewire (Predicate device) | Aristotle Colossus Guidewire (Reference device) |
|---|---|---|---|
| 510(k) Number | K254006 | K233791 | K222437 |
| Regulation | 21 CFR 870.1330 | 21 CFR 870.1330 | 21 CFR 870.1330 |
| Product Code | MOF, DQX | MOF, DQX | MOF, DQX |
| Indications for Use | The Drivewire 35 Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The Drivewire 35 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 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 Colossus 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. |
| Anatomical Location | General intravascular use, including the neuro and peripheral vasculature but not the coronary arteries. | General intravascular use, including the neuro and peripheral vasculature but not the coronary arteries. | General intravascular use, including the neuro and peripheral vasculature but not the coronary arteries. |
| Effective Length | 150-180 cm | 192 cm | 150-300 cm |
| Distal Diameter | 0.035” | 0.024” | 0.035” |
| Core Wire Material | Nitinol | Nitinol | Stainless Steel |
| Proximal Section Material | Stainless Steel | Stainless Steel | Nitinol |
| Radiopaque Coil | 40 cm<br>Nitinol and Nitinol DFT 30% tantalum | 40 cm<br>Nitinol and Nitinol DFT 30% tantalum | 10 cm<br>Platinum wire marker coil |
| Tip Type and Length | Steerable<br>1.6 cm | Steerable<br>1.6 cm | Straight, Shapeable<br>1.0 cm |
| Hydrophilic Coating | 42 cm | 42 cm | 46 cm |
| 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 the 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, bend diameter, and coating length were measured. A visual inspection confirmed there was no damage to the 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 the delivery and retrieval of the guidewire through a 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. |
| 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. |

| Performance Bench Testing | | |
|---|---|---|
| **Test** | **Test Method Summary** | **Results** |
| Kink Resistance | Kink resistance was tested along the guidewire by wrapping the device around mandrels of smaller radii until failure. | All devices met the 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 the 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 the 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 the acceptance criteria of having no damage to the handle or shaft, and equivalent or higher tensile force and measured torque force at slipping compared to the predicate device. |
| Particulate | Particulates were measured under simulated use conditions. | All devices have particulates equivalent to 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 the hydrophilic coating following simulated use was performed. | All devices met the acceptance criteria of having no coating separation after simulated use testing. |
| Radiopacity * | The subject device is manufactured from the same materials and has the same fundamental design as the predicate device, which | Similar radiopacity performance is expected. |

| Performance Bench Testing | | |
|---|---|---|
| **Test** | **Test Method Summary** | **Results** |
| | demonstrated adequate visibility 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. |

* Testing conducted on other representative devices, such as the predicate Drivewire 24 (K233791) with identical or similar materials, design, manufacturing processes, and user interface.

Biocompatibility

Biological risk assessment and testing supports the biocompatibility of the Drivewire 35 Guidewire in accordance with ISO–10993 and consisted of the following:

| **Test** | **Test Description** | **Results** |
|---|---|---|
| Cytotoxicity * | Cytotoxicity study using the 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. |

* These tests were conducted on the predicate Drivewire 24 Guidewire (K233791) and are

referenced to support biocompatibility of the subject device.

Animal Study

No animal studies were conducted, as substantial equivalence of the Drivewire 35 Guidewire to the predicate device is established through the results of non-clinical bench testing.

Sterilization and Shelf Life

The device and its accessories are sterilized using a validated EtO sterilization process in accordance with ISO 11135:2014/AC:2014. The sterilization cycle was validated using the overkill (half-cycle) method to achieve a sterility assurance level (SAL) of $10^{-6}$.

Shelf-life functional testing was conducted on the Drivewire 35 Guidewire using accelerated aging conditions. Testing included simulated use and performance evaluations representative of the intended neurovascular and peripheral use environments. These data support a labeled shelf-life of one (1) year.

**Clinical Testing**

No clinical studies were conducted, as substantial equivalence of the Drivewire 35 Guidewire to the predicate device is established through the results of non-clinical bench testing.

**Conclusion of Substantial Equivalence**

The Drivewire 35 Guidewire has the same intended use and indications for use and similar technological characteristics compared to the predicate Drivewire 24 Guidewire. The differences do not raise new or different questions regarding the safety and effectiveness of the device. The non-clinical bench testing discussed above demonstrates the device performs as intended. Therefore, the subject device is substantially equivalent to the predicate device.