Rapid-Medical Ltd.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

December 14, 2020

Re: K200374
Trade/Device Name: Columbus Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: November 12, 2020
Received: November 12, 2020

Dear Janice Hogan:

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,

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200374

Device Name
Columbus Guidewire

Indications for Use *(Describe)*
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.

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
Device: Columbus Guidewire
K200374

Submission Sponsor

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Date Prepared

December 10, 2020

Device Identification

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

Legally Marketed Predicate Device(s)

Predicate Device: Traxcess 14 Guidewire (K133725)

Indication for Use Statement

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.

Device Description

The Columbus guidewire is a 0.014" 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 Columbus guide wire is comprised of a Nitinol braided flexible distal cable, a proximal shaft, an inner core wire and a handle. The braided cable is attached to the proximal shaft via inner connector. The inner core wire runs inside the shaft and the cable from the distal end of the cable to the handle. The distal end of the inner core wire is flattened, looped around and joined to the tip of the distal cable, forming a deflectable tip. In order to actuate the tip deflection in two directions, the Columbus guidewire handle contains a tube assembly section which enables continuous stroke by a self-locking feature. 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. Two models are available, Columbus LR (large radius) PN: GWPP4464 which has radius curvature of 4mm and Columbus SR (small radius) PN: GWPP4463 which has radius curvature of 2mm. The Columbus guidewire is provided with a torque accessory to facilitate use of the guidewire and is not intended to contact the patient's body.

Substantial Equivalence Discussion

The table below compares the Columbus guidewire to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The Columbus guidewire does not raise any new questions compared to the predicate based on this comparison.

	Columbus Guidewire (Subject device)	**Traxcess 14 Guidewire (Predicate device)**
510(k) Number	K200374	K133725
Regulation	21 CFR 870.1330	21 CFR 870.1330
Product Code	MOF, DQX	MOF, DQX

	Columbus Guidewire (Subject device)	**Traxcess 14 Guidewire (Predicate device)**
Indications for Use	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.	The Traxcess 14 Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered 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
Overall Length	200 cm	200 cm
Proximal Diameter	0.014”	0.014”
Distal Diameter	0.014”	0.012”
Distal Section Length	43 cm	60 cm
Core Wire Material	Nitinol	Nitinol
Proximal section Material	Stainless Steel	Stainless Steel
Coil Length	43 cm	40 cm
Coil Material	Nitinol and Nitinol DFT 30% tantalum/ DFT 40% Platinum	Stainless steel and platinum
Shapeable Tip Length	2 cm (Columbus LR GWPP4464) 1.5 cm (Columbus SR GWPP4463)	1.4 cm
Radiopaque Tip Length	2 cm (Columbus LR GWPP4464) 1.5 cm (Columbus SR GWPP4463)	3 cm

	Columbus Guidewire (Subject device)	Traxcess 14 Guidewire (Predicate device)
Tip shaping	In situ tip deflection mechanism, controlled by the user in the proximal end of the device	Manual shaping of the tip prior to device delivery
Coating	No coating	Hydrophilic coating (SLIP-COAT)
Sterilization	Sterile	Sterile
Sterilization Method	Ethylene oxide	Ethylene oxide
Single Use	Yes	Yes
Packaging	Placed into a Dispenser hoop, Tyvek pouch, and Carton box	Placed into a Dispenser hoop, Tyvek pouch, and Carton box

Non-Clinical Performance Data

As part of demonstrating substantial equivalence to the predicate devices, Rapid-Medical Ltd. completed a number of non-clinical performance tests. The device meets all the requirements of overall design, sterilization, and biocompatibility. Testing results confirm that the design output meets the design inputs for the device.

Biocompatibility

The materials used in the manufacture of the subject device Columbus Guidewire, are identical to those used in the manufacturing of Rapid-Medical Neurovascular device, Comaneci Embolization Assist Device (DEN170064) that was granted on April 24th, 2019. The two devices share the same manufacture process and same manufacture environment. In addition, the two devices are intended to be used in the same anatomical locations, and identical in terms of frequency and duration of exposure.

Biocompatibility testing was completed for Comaneci device in accordance with ISO 10993 and consisted of the following tests: Cytotoxicity, Irritation (Intracutaeous reactivity), Sensitization, Hemocompatibility, Pyrogenicity, Acute Systemic and Toxicity Testing. Direct hemolysis, Direct contact complement activation, Ames Mutagenicity and In vivo Thrombogenicity tests were performed directly with the subject device. All tests confirmed biocompatibility.

Sterilization and Shelf life

The device and its accessories, are sterilized by 100% Ethylene Oxide and have been adopted into a validated sterilization process in accordance with the principles of EN 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"). This statement is supported by standards assessment conducted by Rapid-Medical Ltd.

The device is *non-pyrogenic*, a complete endotoxin evaluation demonstrated endotoxin level below 2.15 EU/device supporting non-pyrogenicity, endotoxin testing will be conducted on every batch.

The accelerated shelf life testing for Columbus Guidewire has been conducted (T=2.5 years accelerated aging) with test results confirmed that all acceptance criteria were met.

Bench Tests

The device passed all 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.

Non-Clinical Performance Tests

Performance Bench Testing		
Test	**Standards**	**Results**
Visual and Dimensions Verification	FDA Guidance for Industry and Food and Drug Administration Staff: Coronary, Peripheral, and Neurovascular Guidewires Performance Tests and Recommended Labeling, October 2019 (thereinafter, "FDA Guidewire Guidance"), Section G-3	Pass
Tip Flexibility	FDA Guidewire Guidance, Section G-15	Pass
Simulated Use-Delivery and Retrieval Force	FDA Guidewire Guidance, Section G-5	Pass
Simulated Use Model Testing and Product Compatibility	FDA Guidewire Guidance, Section G-5	Pass
Torqueability	FDA Guidewire Guidance, Section G-9	Pass
Kink Resistance	FDA Guidewire Guidance, Section G-14	Pass
Fracture Test	ISO11070 section 8.4	Pass
Flexing Test	ISO11070 section 8.5	Pass
Tensile Force	FDA Guidewire Guidance, Section G-6	Pass
Torque Strength	FDA Guidewire Guidance, Section G-8	Pass
Particulate	FDA Guidewire Guidance, Section G-11	Pass
Corrosion	FDA Guidewire Guidance, Section G-13	Pass

Additional two bench test were designed to support subject device in situ tip bending mechanism.

Test	Description	Results
Tip deflection force	The maximum tip deflection force was measured during complete deflection in a simulated vessel diameter range of 0.5-5.5mm to verify it is within justifiable safe range	Pass
Deflectable tip cyclic fatigue testing	Testing was conducted to determine the tip deflection mechanism durability to 30 full handle actuations	Pass

Pre-Clinical Animal Testing Data

As part of demonstrating the substantial equivalence to the predicate device, Rapid-Medical Ltd. completed two controlled GLP studies in domestic swine with the Columbus device and the predicate device. Usability, performance, and acute vascular safety were assessed in the first study, whereas the second study assessed acute safety and thromboresistance.

Acute procedural safety showed no device perforations or dissections or regional vascular thrombus assessed angiographically in either study. Regional device-contacting thrombus was evaluated in accordance with recognized standards and guidelines in the second study and was also negative for both devices. Downstream macroscopic assessment of renal capsule, parenchyma, and native renal artery were also absent thrombi at the acute term assessment. In terms of usability and performance the following attributes were assessed: deliverability, visibility, controllability level, general impression, interface with accessory devices, radiopacity, intuitive actuation, device removal, ease of use, ergonomics, and device integrity. The usability and performance results of the first study demonstrate comparable performance for both devices. Therefore in 2 adequate and well controlled GLP studies, utilizing a total of 5 swine, assessments by well qualified experts in accordance with recognized methods, standards, and guidelines show that safety, performance, usability, and thromboresistance of the Columbus guidewire is substantially equivalent to Traxcess 14.

Statement of Substantial Equivalence

The Columbus device has the same intended use and indications for use, and similar technological characteristics compared to the Traxcess 14 predicate device. The minor differences do not raise different questions compared to the predicate, and the bench

and animal testing discussed above demonstrates that these differences do not adversely impact performance. Therefore, the device is substantially equivalent to the predicate device.