January 7, 2025

OrbusNeich Medical (Shenzhen) Co., Ltd.
Dora Zhang
FDA Supervisor of Regulatory Affairs
No.1 Jinkui Road
Futian Free Trade Zone
Shenzhen, 518038, China

Re: K242588
Trade/Device Name: COREPASS Modular Microcatheter (FLEX); COREPASS Modular Microcatheter (CONTROL)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: August 30, 2024
Received: December 6, 2024

Dear Dora Zhang:

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.

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,

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242588

Device Name
COREPASS Modular Microcatheter (FLEX) and COREPASS Modular Microcatheter (CONTROL)

Indications for Use *(Describe)*
The COREPASS FLEX/CONTROL microcatheters are indicated for:
• supporting and facilitating the placement of guidewires in the coronary and peripheral vasculature (not intended for neurovasculature).
• exchanging guidewires in the coronary and peripheral vasculature.
• the delivery of contrast media into the coronary, peripheral, and abdominal vasculature.

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

This 510(k) Summary is submitted in accordance with 21 CFR 807.92.

Submitter:	OrbusNeich Medical (Shenzhen) Co., Ltd. No.1 Jinkui Road Futian Free Trade Zone Shenzhen 518038, China Phone: +86-755-83580181-8326 Fax: +86-755-83580169
Contact Person:	Name: Dora Zhang Job Title: FDA Supervisor of Regulatory Affairs Email: dorazhang@orbusneich.com
Date Prepared:	August 27, 2024
Device:	Name of Device: COREPASS Modular Microcatheter Common Name: Microcatheter Classification Name: Percutaneous catheter (21 CFR 870.1250) Regulatory Class: II Product Code: DQY
Predicate Device:	Teleport XT Microcatheter (K231608, DQY, cleared Jan 7, 2024) This predicate has not been subject to a design-related recall.
Reference Devices:	Teleport Microcatheter (K182360, DQY, cleared Nov 9, 2018) Turnpike LP Catheter (K191560, DQY, cleared Aug 09, 2019)
Device Description:	The COREPASS FLEX/ CONTROL microcatheters are singe lumen catheters, offered in two shaft sizes (2.2F and 2.5F) with working lengths of 135cm or 150cm, designed for use in coronary, peripheral, and abdominal vasculature. The COREPASS FLEX/CONTROL share identical shaft profile 2.5F (0.032'') but different distal profile, including 2.2F (0.028'') for the 2.2F configuration (COREPASS FLEX) and 2.5F (0.032'') for the 2.5F configuration (COREPASS CONTROL). The catheter consists of five sections: hub with a female luer connector, catheter body

shaft, proximal section, distal section, and tip. The distal most 60cm of the outer surface is coated with a hydrophilic polymer to increase lubricity and the lumen of catheter is lined with a fluoropolymer to facilitate movement of the guidewire. The catheter is compatible with a standard 0.014 inch (0.36mm) guidewire.

Indications For Use: The COREPASS FLEX/CONTROL microcatheters are indicated for:

- supporting and facilitating the placement of guidewires in the coronary and peripheral vasculature (not intended for neurovasculature).
- exchanging guidewires in the coronary and peripheral vasculature.
- the delivery of contrast media into the coronary, peripheral, and abdominal vasculature.

Technological Characteristics: The subject device has the following similarities to the predicate devices:

- Same indications for use
- Similar catheter design
- Similar materials of construction
- Same hydrophilic coating
- Same method of sterilization

The following technological differences exist between the subject and predicate device:

- specific materials selected
- exact dimensions of components

Performance Data: The following performance data were provided in support of the substantial equivalence determination.

- Sterilization
- Shelf-Life
- Performance Testing
  - Particulate Evaluation
  - Visual Inspection
  - Dimension Inspection
  - Media Flow Rate
  - Shaft Vacuum/ Leak Test
  - Simulated Use
  - Shaft Burst Pressure
  - Guidewire Compatibility
  - Coating Integrity

- Flexibility and Kinking
- Corrosion Resistance
- Torque Strength
- Tensile Strength
- Radiopacity

- Biocompatibility testing
  - Cytotoxicity
  - Sensitization
  - Intracutaneous Reactivity
  - Acute Systemic Toxicity
  - Hemocompatibility
    - Direct and Indirect Hemolysis
    - Complement Activation (SCb5-9)
    - In vitro Thrombogenicity
  - Material Mediated Pyrogenicity

The test results of COREPASS Modular Microcatheter met all acceptance criteria, which are same or similar to the predicate device and reference device. It ensures that the design and construction of COREPASS Modular Microcatheter are suitable for its intended use.

Conclusion: This information supports a determination of substantial equivalence between the COREPASS Modular Microcatheter and the predicate device described above.