April 10, 2026

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

Re: K253361/S001
Trade/Device Name: Teleport Glide Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 29, 2025
Received: March 6, 2026

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 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,

LYDIA S. GLAW -S
Digitally signed by LYDIA S. GLAW -S
Date: 2026.04.10 13:19:02 -04'00'

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)*
K253361

Device Name
Teleport Glide Microcatheter

Indications for Use *(Describe)*
Teleport Glide Microcatheter is indicated for guiding and supporting a guidewire within the peripheral vasculature, allowing for the exchange of guidewires and delivery contrast media into peripheral vascular.

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.

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: Manager of Regulatory Affairs Email: dorazhang@orbusneich.com
Date Prepared:	September 29, 2025
Device:	Name of Device: Teleport Glide Microcatheter Common Name: Microcatheter Classification Name: Percutaneous catheter (21 CFR 870.1250) Regulatory Class: II Product Code: DQY
Predicate Device:	Navicross 0.018" (K173799, DQY, cleared March 29, 2018) Terumo Support Catheter (K110540, DQY, cleared May 13, 2011) R2P Navicross (K231044, DQY, cleared July 27, 2023)
Device Description:	The Teleport Glide Microcatheters are single lumen catheters, offered in three sizes, with working lengths of 65cm, 90cm, 135cm, 150cm, 180cm and 200cm, with two tip shapes available, designed for use in the peripheral vasculature. The catheter consists of four primary sections: hub, shaft, distal section and a radiopaque tip. The outer surface of the catheter is coated with a hydrophilic polymer to increase lubricity and the lumen of the catheter is lined with fluoropolymer to facilitate movement of the guidewire. The catheter is compatible with a standard 0.018-inch(0.46mm) or 0.035-inch(0.89mm) guidewire.
Indications For Use:	Teleport Glide Microcatheter is indicated for guiding and supporting a guidewire within the peripheral vasculature,

allowing for the exchange of guidewires and delivery contrast media into peripheral vascular.

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 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
  - Flexibility
  - Shaft Vacuum/ Leak Test
  - Shaft Burst Pressure
  - Simulated Use
  - Kink Resistance
  - Tensile
  - Coating Integrity
  - Tip Durability
  - Corrosion Resistance
  - Radiopacity
- Biocompatibility testing
  - Cytotoxicity
  - Sensitization
  - Intracutaneous Reactivity
  - Acute Systemic Toxicity
  - Hemocompatibility
    - Direct and Indirect Hemolysis
    - Complement Activation (SCb5-9)
    - Partial Thromboplastin Time (PTT) with

Sponsor- (Supplied Comparison Article) (GLP)

- In vitro Thrombogenicity

- Material Mediated Pyrogenicity

The test results of Teleport Glide Microcatheter met all acceptance criteria. It ensures that the design and construction of Teleport Glide Microcatheter are suitable for its intended use.

Conclusion: This information supports a determination of substantial equivalence between the Teleport Glide Microcatheter, and the predicate device described above.