November 9, 2018

OrbusNeich Medical Trading Inc.
John Pazienza
General Manager and Senior Director, Engineering
5363 NW 35th Avenue
Fort Lauderdale, Florida 33060

Re: K182360
Trade/Device Name: Teleport Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: August 29, 2018
Received: August 30, 2018

Dear John Pazienza:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
2018.11.09 15:20:29
-05'00'

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*

K182360

Device Name
Teleport Microcatheter

Indications for Use *(Describe)*

The Teleport microcatheters are indicated for:

- supporting and facilitating the placement of guidewires in the coronary and peripheral vasculature.
- 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.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Submitter:	OrbusNeich Medical Trading, Inc. 5363 NW 35th Avenue Fort Lauderdale, FL 33309 Phone: 954.730.0711 Fax: 954.730.7601
Contact Person:	John D. Pazienza
Date Prepared:	August 29, 2018
Trade Name:	Teleport Microcatheter
Common Name:	Microcatheter
Classification Name:	Percutaneous Catheter 21 CFR 870.1250
Product Code:	DQY
Device Class:	Class II
Predicate Device:	ASAHI Corsair Pro (K161126; DQY; cleared August 25, 2016)
Reference Devices:	Terumo Finecross MG (K082519; cleared September 26, 2008) OrbusNeich Sapphire NC Plus (K162209; cleared October 6, 2016)
Device Description:	The Teleport family of microcatheters are single lumen catheters, offered in two shaft sizes (2.0F and 2.1F) with working lengths of 135cm or 150cm, designed for use in the coronary, peripheral, and abdominal vasculature. The shaft profiles gradually decrease from 2.6F (0.034") to 2.0F (0.0265") for the 2.0F configuration (Teleport), and 2.7F (0.036") to 2.1F (0.0275") for the 2.1F configuration (Teleport Control) respectively. The catheter consists of four sections: body shaft, proximal tip shaft, distal tip shaft, and a radiopaque tip. The distal most 60cm of the outer surface is coated with a hydrophilic polymer to increase lubricity and the lumen of the 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.
Intended Use:	The Teleport microcatheters are indicated for: • supporting and facilitating the placement of guidewires in the coronary and peripheral vasculature. • exchanging guidewires in the coronary and peripheral vasculature. • the delivery of contrast media into the coronary, peripheral, and abdominal vasculature.

Technological Characteristics: At a high level, the subject and predicate devices are based on the same technological elements:

- the same indications for use
- catheter design
- hydrophilic coating
- 0.014" guidewire compatibility
- 4F guiding catheter compatibility
- Maximum allowable pressure of 300 psi
- EO sterilization

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

- specific materials selected
- exact dimensions of components and catheter
- permissible rotations

Performance Data: Testing was performed to support the use of the Teleport microcatheter:

- Sterilization
- Shelf-Life
- Performance Testing
  - Visual Inspection
  - Dimension Inspection
  - Flow Rate
  - Simulated Use
  - Vacuum Leakage
  - Shaft Burst Pressure
  - Torque Strength
  - Flexibility and Kinking
  - Radiopacity
  - Corrosion Resistance
  - Guidewire Compatibility
  - Bond Strength
  - Tip Strength
  - Coating Integrity
  - Particulate Evaluation
- Biocompatibility
  - Cytotoxicity
  - Sensitization
  - Intracutaneous Reactivity
  - Acute Systemic Toxicity
  - Hemocompatibility
    - Hemolysis
    - Partial Thromboplastin Time
    - Complement Activation
    - In vivo Thromboresistance
  - Pyrogenicity
  - Genotoxicity

The Teleport microcatheter test results met all acceptance criteria and were similar to the predicate and reference devices.

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