October 20, 2022

Cruzar Medsystems Inc
Adrienne Foller
Consultant
Strategic Quality Solutions LLC
1594 E Monaco Ave
Salt Lake City, Utah 84121

Re: K213466
Trade/Device Name: Houdini Cross Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: January 13, 2022
Received: January 18, 2022

Dear Adrienne Foller:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213466

Device Name
Houdini Cross Support Catheter

Indications for Use *(Describe)*
The Houdini Cross Support Catheter is intended to be used in conjunction with a steerable guidewire to access discrete regions of the peripheral vasculature and for guidewire exchange.

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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510(k) Summary

Cruzar Medsystems, Inc.
Houdini® Cross Support Catheter

1. MANUFACTURER AND SUBMITTER

Company Name: Cruzar Medsystems, Inc.

Company Address: 50 Braintree Hill Office Park, Suite 301
Braintree, MA 02184
Telephone: 781-223-0508

Contact Person: Adrienne von Foller, Strategic Quality Solutions, LLC
Regulatory Consultant
Telephone: 801-916-8188
Email: Adrienne@device2market.com

Date Prepared: 26 October 2021

2. DEVICE NAME AND CLASSIFICATION

Trade Name: Houdini® Cross Support Catheter
Common Name: Percutaneous catheter
Model Numbers: CM-3502, CM-3602
Classification Name: Percutaneous catheter
Regulation Number: 21 CFR 870.1250
Regulatory Class: II
Product Code: DQY

3. PREDICATE DEVICE

Device Name: Houdini® Catheter
510(k) Applicant: Cruzar Medsystems, Inc.
510(k): K151896
There has been no recall on the Cruzar Medsystems Houdini® Catheter device.

4. REFERENCE DEVICE

Device Name: XO Cross Support Catheter
510(k) Applicant: Transit Scientific
510(k): K193420
There has been no recall on the Transit Scientific XO Cross Support Catheter.

5. DEVICE DESCRIPTION

The Houdini® Cross Support Catheter is a single use, bi-lumen intravascular catheter intended for percutaneous use. The Houdini® Cross Support Catheter is intended for use in the iliac, femoral, ilio-femoral and popliteal arteries. It is designed for use in conjunction with a standard commercially available off the shelf (OTS) 0.014" – 0.018" guidewire (not included) to gain access to locations within the cardiovascular system that are remote from the site of insertion. Once accessed, guidewires may be exchanged within the catheter. In addition, the Houdini® Cross Support Catheter provides the option of distal anchoring as well as physician-controlled extension of the inner shaft (up to 2 cm) to support the OTS guidewire during advancement.

The effective length of the Houdini® Cross Support Catheter is a nominal 100 cm. The inner lumen accommodates an OTS 0.014" – 0.018" spring-tipped guidewire. The inner lumen shaft allows for visualization under fluoroscopy due to the radiopaque stainless-steel design and additionally allows for continuous clinician control of the OTS guidewire for appropriate positioning.

If distal anchoring is desired, the Houdini® Cross Support Catheter requires the use of a commercially available OTS manual inflation device (not included). Once positioned within 2 cm of the user's target location, the catheter is inflated to 6 atm using diluted radiopaque contrast media to anchor the distal end of the catheter in the blood vessel. For additional support of the guidewire, the clinician may extend the location of the inner lumen shaft up to 2 cm distally without the need to reposition the anchoring balloon.

6. INDICATIONS FOR USE

The Houdini® Cross Support Catheter is intended to be used in conjunction with a steerable guidewire to access discrete regions of the peripheral vasculature and for guidewire exchange.

The intended use and indications for use of the modified device are the same as the cleared, legally marketed predicate device (K151896) and reference device (K193420).

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Houdini® Cross Support Catheter and the predicate Houdini® Catheter (K151896) are both sterile, single-use devices designed to access discrete regions of the peripheral vasculature. A comparison of the technological characteristics of the subject device, the predicate Houdini® Catheter (K151896), and the reference XO Cross Support Catheter (K193420) is described below in Table 1.

Table 1: Comparison of the Subject, Predicate, and Reference Devices

Characteristic	Subject Device Houdini Cross Support Catheter	Predicate Device Houdini Catheter (K151896)	Reference Device XO Cross Support Catheter (K193420)
Indications for Use	Intended to be used in conjunction with a steerable guidewire to access discrete regions of the peripheral vasculature and for guidewire exchange.	Intended to be used in conjunction with a steerable guidewire to access discrete regions of the peripheral vasculature and for guidewire exchange.	Intended to guide and support a guidewire during access of the peripheral vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.
Guidewire Compatibility	0.014" - 0.018"	0.014" - 0.035"	0.014" - 0.035"
Sheath Compatibility	6 Fr	6 Fr	4 Fr
Catheter Outer Diameter	5 Fr	5 Fr	2 Fr – 4 Fr
Catheter Effective Length	100 cm	100 cm	90, 135, 150, 175 cm
Labeled Balloon Diameter	5mm 6mm	4mm 5mm 6mm 7mm 8mm	No balloon component
Balloon Length	2 cm	2 cm	
Anchoring Inflation Pressure	6 atm	6 atm	
Maximum Working Pressure	9 atm	12 atm	
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

8. PERFORMANCE DATA

The following performance testing has been completed in support of the substantial equivalence determination, including bench testing, biocompatibility, and simulated use testing.

Biocompatibility Testing

The biocompatibility evaluation for the Houdini® Cross Support Catheter was conducted in accordance with the FDA Guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process” dated September 04, 2020. The biological evaluation included the following:

- Material characterization
- Cytotoxicity
- Sensitization
- Irritation
- Material-mediated Pyrogenicity
- Acute Systemic Toxicity
- Hemocompatibility: Hemolysis, Direct and Extract Methods
- Hemocompatibility: Partial Thromboplastin Time
- Hemocompatibility: Platelet and Leukocyte Count
- Hemocompatibility: Complement Activation

Simulated Use Testing

The Houdini® Cross Support Catheter was subjected to simulated use testing to verify ability to access discrete regions of the peripheral vasculature and for guidewire exchange. Test results indicate that the device satisfies simulated use testing requirements when used as indicated.

Performance Bench Testing

The Houdini® Cross Support Catheter has completed the following performance bench tests per ISO 10555-1. Test results indicate that the device satisfies functional performance requirements when used as indicated.

- Dimensional verification
- Crossing profile
- Radiopacity
- Corrosion resistance
- Tensile strength
- Pressurization performance
- Freedom from leakage
- Inflation fatigue
- Torque load
- Kink resistance
- Particulate testing

9. CONCLUSIONS

A comparison of the design and technological characteristics between the Houdini® Cross Support Catheter and the predicate Houdini® Catheter demonstrates substantial equivalence. The performance data for the subject device, including biological evaluation, bench testing, and simulated use, further supports the substantial equivalence of the Houdini® Cross Support Catheter.