



Food and Drug Administration
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December 7, 2015

Cruzar Medsystems, Inc.
Ms. Gina To
Regulatory Consultant
50 Braintree Hill Office Park, Suite 301
Braintree, MA 02184

Re: K151896
Trade/Device Name: Houdini Catheter
Regulation Number: 21 CFR 870.1250
Regulatory Class: Class II
Product Code: DQY
Dated: October 19, 2015
Received: October 22, 2015

Dear Ms. To:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151896

Device Name

Houdini Catheter

Indications for Use (Describe)

The Cruzar Medsystems Houdini 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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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“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

Cruzar Medsystems Houdini™ 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: Gina To, Regulatory Consultant
Date Prepared: November 23, 2015

2. DEVICE NAME AND CLASSIFICATION

Trade Name: Houdini™ Catheter
Model Numbers: CM-3400, CM-3500, CM-3600, CM-3700, CM-3800
Classification Name: Percutaneous catheter
Regulation Number: 21 CFR 870.1250
Regulatory Class: II
Product Code: DQY

3. PREDICATE DEVICE

Device Name: ENDOCROSS, ENABLER-P CATHETER, 1000 PART
NUMBER: 1160
510(k) Applicant: ENDOCROSS, LTD
510(k): K083833

There has been no recall on the Endocross Enabler-P device.

4. DEVICE DESCRIPTION

The Houdini Catheter is a single use, dual-lumen intravascular catheter intended for percutaneous use. It is designed for use in conjunction with a 0.014" – 0.035" guide wire to gain access to locations within the cardiovascular system that are remote from the site of insertion. Once accessed, guide wires may be exchanged within the catheter. In addition, the Houdini Catheter can provide distal anchoring and supports the advancement of the guidewire.

The effective length of the Houdini Catheter is a nominal 100cm. The distal tip incorporates a radiopaque marker to aid in visualization under fluoroscopy. The inner

diameter of the Houdini Catheter shaft will accommodate a standard commercially available 0.014” – 0.035” guidewire.

The balloon catheter is inflated to 6atm with radiopaque contrast media with a standard manual inflator to anchor the catheter. Internal forces are placed on the inner lumen to the point that it grips and stabilizes the guidewire. Once pressurized to 6 atm, the guidewire is advanced by manual control of the proximal Y-connector by the physician.

The Houdini Catheter requires the use of traditional manual inflation devices (not included).

5. INTENDED USE/INDICATIONS FOR USE

The Houdini 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 Houdini Catheter is indicated for use in the iliac, femoral, ilio-femoral and popliteal arteries.

The intended use and indications for use for the subject device are the same as the predicate device.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Houdini Catheter and the predicate Endocross Enabler-P Catheter (K083833) are both sterile, single-use devices designed to access discrete regions of the peripheral vasculature. The mechanism of operation of the non-therapeutic inflatable balloon elements at the distal tip of the Houdini Catheter is similar to the Enabler and facilitates stability, visual orientation and placement of the central guidewire. The Houdini Catheter has the same intended use and indication for use as the Enabler.

A comparison the technological characteristics of the Houdini Catheter and the predicate Endocross Enabler-P Catheter (K083833) is tabulated below.

Characteristic	Houdini Catheter – Subject Device	Predicate Device Endocross, Enabler-P Catheter (K083833)
Intended 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
Nominal Balloon Diameter	Model CM-3400: 4mm Model CM-3500: 5mm Model CM-3600: 6mm	6mm

Characteristic	Houdini Catheter – Subject Device	Predicate Device Endocross, Enabler-P Catheter (K083833)
	Model CM-3700: 7mm Model CM-3800: 8mm	
Catheter Effective Length	100cm	103cm
Maximum Balloon Working Length	2cm	2cm
Anchoring Inflation Pressure	6atm	1.5atm
Maximum Working Pressure	12atm	6atm
Rated Burst Pressure	16atm	10atm
Catheter Shaft Diameter	5Fr	5Fr
Guidewire Size	0.014 - 0.035 inches	0.035 inches
Introducer Sheath Size	6Fr	7Fr
Peak Force Delivery	0.35kgf to 0.71kgf	0.026Kgf to 0.185
Sterilization Method	Ethylene Oxide	Ethylene Oxide

7. PERFORMANCE DATA

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

Biocompatibility Testing

The biocompatibility evaluation for the Houdini Catheter was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing’” May 1, 1995, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The battery of testing included the following tests: cytotoxicity, sensitization, irritation, systemic toxicity, genotoxicity, hemocompatibility, and thrombogenicity. Biocompatibility test results indicate that the device materials are biocompatible.

Simulated Use Testing

The Houdini Catheter was subjected to simulated use testing to assess device insertion, deployment and device removal.

Performance Bench Testing

The Houdini Catheter has completed the performance bench tests as listed below. Test results indicate that the device satisfies functional performance requirements when used as indicated.

- Simulated use validation
 - Device insertion, deployment, removal
 - Surface, Distal Tip, ISO 10555-1
 - Introducer sheath sizing
- Radio-detectability, ASTM F640-12
- Peak tensile force, ISO 10555-1 Annex B
- Pressurization Performance
 - Freedom from fluid leakage, ISO 10555-1 Annex C
 - Freedom from Air leakage, Hubs, ISO 10555-1 Annex D
 - Burst pressure, ISO 10555-1 Annex F
 - Inflation pressure vs. diameter
 - Peak delivery force versus inflation pressure
- Dimensional verification
- Tensile strength
- Torque load
- Crossing Profile
- Kink Resistance

8. CONCLUSIONS

A comparison of the technological characteristics between the Houdini Catheter and the predicate Endocross, Enabler-P Catheter shows that they are largely similar. While there are some differences in technological characteristics between the subject device and the predicate device, these differences do not raise new questions of safety or effectiveness. The performance data for the Houdini Catheter demonstrate that it should perform as intended for the indicated use, the same indicated use as the predicate device. Therefore, the subject device is substantially equivalent.