February 8, 2021

MEDRAD Interventional/Possis
Doug Atkins
Sr. Regulatory Affairs Associate
9055 Evergreen Blvd NW
Minneapolis, Minnesota 55433

Re: K101354
Trade/Device Name: Fetch 2 Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Doug Atkins:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 21, 2011. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.02.08 07:58:33 -05'00'

Gregory O'Connell
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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MEDRAD Interventional / Possis
c/o Mr. Doug Atkins
Sr. Regulatory Affairs Associate
9055 Evergreen Blvd
Minneapolis, MN 55433-8003

JAN 21 2011

Re: K101354
Trade/Device Name: Fetch 2 Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: DXE
Dated: December 28, 2010
Received: December 29, 2010

Dear Mr. Atkins:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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): K101354

Device Name: Fetch® 2 Aspiration Catheter

Indications for Use:

The Fetch 2 Aspiration Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the peripheral and coronary vasculature.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101354

K101354

JAN 21 2011

Section 5 – 510(k) Summary

Submitter:	MEDRAD Interventional / Possis 9055 Evergreen Boulevard NW Minneapolis, MN 55433-8003 USA
Contact Person:	Doug Atkins Sr. Regulatory Affairs Associate Phone: (763) 450-8060 Fax: (763) 780-2227 Email: doug.atkins@possis.com
Date Submitted:	May 13, 2010
Trade Name:	Fetch® 2 Aspiration Catheter
Classification:	870.5150
Product Code:	DXE
Predicate Device(s):	Fetch Aspiration catheter: K081989 MEDRAD Interventional / Possis 9055 Evergreen Boulevard N.W. Minneapolis, MN 55433-8003
Device Description:	The Fetch 2 Aspiration Catheter is a rapid exchange, low-profile tip, dual lumen catheter that uses a 0.014" (0.36 mm) guide wire to track to the target site. It is used for aspiration of fresh, soft emboli and thrombi. Its outer diameter (0.056" or 4F) allows advancement to the target site through a 6F (0.070" I.D.) guiding catheter. A radiopaque marker is located near the distal tip. Fetch 2 is provided with an extension line (connected to a one-way stopcock), 2 - 30 cc syringes, and 2 - 40 micron collection baskets. The baskets can be used to filter aspirated blood for laboratory analysis of collected thrombus.
Intended Use:	The Fetch 2 Aspiration Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the peripheral and coronary vasculature.
Performance Data:	Bench and laboratory testing was performed to support a determination of substantial equivalence to the predicate device. Results from the testing provide assurance that the proposed device conforms to the requirements for its intended use. This included the following tests: • Biocompatibility o Cytotoxicity (ISO 10993-5) o Intracutaneous Reactivity (ISO 10993-10) o Sensitization (ISO 10993-10) o Acute Systemic Toxicity (ISO 10993-11) o Material Mediated Pyrogen (ISO 10993-11) o Physiochemical (ISO 10993-18) o Hemocompatibility - ASTM Hemolysis (ISO 10993-4) - Partial Thromboplastin Time Assay (ASTM F2382-04)

- C3a Complement Activation (ISO 10993-4)
- SC5b-9 Complement Activation (ISO 10993-4)
- Thromboresistance (ISO 10993-4)

- Package integrity
- Sterilization testing
- Dimensional testing
- Operational characteristics
- Aspiration testing
- Tracking
- Mechanical integrity
- Kink resistance

Conclusion: MEDRAD Interventional / Possis considers the Fetch 2 Aspiration Catheter to be substantially equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and principles of operation.