May 20, 2021

Concentric Medical, Inc.
Kirsten Valley
Senior VP, Technology & Regulatory Affairs
301 E. Evelyn Ave.
Mountain View, California 94041

Re: K091703
Trade/Device Name: HD Guide Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Kirsten Valley:

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 October 14, 2009. Specifically, FDA is updating this SE Letter as an administrative correction 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: 2021.05.20 09:42:07 -04'00'

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 –WO66-G609
Silver Spring, MD 20993-0002

Concentric Medical
C/O Ms. Kirsten Valley
Sr. Vice President, Technology & Regulatory Affairs
301 East Evelyn Ave.
Mountain View, CA 94041

OCT 1 4 2009

Re: K091703
Trade Name: Concentric HD Guide Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: DXE
Dated: September 18, 2009
Received: September 21, 2009

Dear Ms. Valley:

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.

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 STATEMENT

INDICATIONS FOR USE

510(k) Number (if known): This application K091703

Device Name: HD Guide Catheter

Indications for Use: The HD Guide Catheter is indicated for the removal/aspiration of fresh, soft emboli and thrombi from vessels in the arterial system.

Prescription Use _X_ (Per 21 CFR 801.109) AND/OR Over-The-Counter Use_____ (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091703

510(K) SUMMARY

General Information

Trade Name	HD Guide Catheter
Common Name	Embolectomy Catheter
Classification	Embolectomy Catheter, 21CFR 870.5150 – Class II
Submitter	Concentric® Medical, Inc. 301 E. Evelyn Avenue Mountain View, CA 94041 Tel 650-938-2100 Fax 650-938-2700
Contact	Kirsten Valley Senior Vice President, Technology and Regulatory Affairs

OCT 14 2009

Intended Use

The HD Guide Catheter is indicated for the removal/aspiration of fresh, soft emboli and thrombi from vessels in the arterial system.

Predicate Device

QuickCat Extraction Catheter (K073519).

Device Description

The HD Guide Catheter consists of a single lumen, braided, variable stiffness shaft with a radiopaque marker on the distal end and a luer hub on the proximal end. The catheter shaft has a hydrophilic coating to reduce friction during use. A rotating hemostatic valve with side-arm adapter is provided with each catheter.

Materials

All materials used in the manufacture of the HD Guide Catheter are suitable for the intended use of the device and have been used in numerous previously cleared products.

Testing Summary

The results of verification and validation conducted on the HD Guide Catheter demonstrate that it performs as designed, is suitable for its intended use and is substantially equivalent to the predicate device.

Summary of Substantial Equivalence

The HD Guide Catheter is substantially equivalent to the predicate device with regard to device design, intended use, and patient population. Any differences in technological characteristics between the HD Guide Catheter and the predicate device do not raise any new issues of safety or effectiveness.