

510(k) SUMMARY

K081725

A. Submitter Information:

Submitter: MEDCOMP®
 1499 Delp Drive
 Harleysville, PA 19438
 Tel: (215) 256-4201
 Fax: (215) 256-9191

Contact: Lisa Weikert
 Regulatory Specialist

Date Prepared: June 20, 2008

B. Trade Name: .010" Vascular Guidewires

Common Name: Guidewires
 Classification Name: Catheter Guide wire
 Product Code: DQX
 C.F.R. Section: 21 CFR 870.1330

C. Predicate Device:

Lake Region Hydrophilic Guidewire (K040825) - Lake Region Medical*
 Hydrophilic Guidewire (K033758) - Lake Region Medical*
 Mandrel Guidewires (K011084) - Lake Region Medical*
 *(formerly Lake Region Manufacturing, Inc.)

D. Device Description:

The Medcomp .010" Vascular Guidewires are sterile, single-use devices used to facilitate intravascular medical device insertion. The proposed devices will be packaged and labeled as sterile accessories in individual pouches, or as part of kit configurations.

The Medcomp .010" guidewires consist of a stainless steel core wire, which forms the proximal shaft of the guidewire – reducing in size from the proximal to the distal end, with a smooth transition to the coiled floppy distal tip secured to the end of the core.

The .010" Vascular Guidewires have an outside diameter of 0.010" and are available in 45, 80 and 120cm lengths, with coil lengths of 4cm or 9.5cm. The .010" Vascular Guidewires are uncoated, or are available with a hydrophilic coating or a silicone fluid coating. The hydrophilic and silicone coatings reduce friction during use. Radiopacity of the distal coil region facilitates fluoroscopic visualization.

E. Intended Use:

The Medcomp .010" Vascular Guidewires are indicated for general intravascular use, including the peripheral vasculature, to facilitate the selective placement of medical devices in the vessel anatomy.

This device is not intended for coronary or cerebrovascular use.

F. Comparison to Predicate Device:

The technological characteristics of the .010" Vascular Guidewire are substantially equivalent to the predicate devices in terms of intended use, general design, functionality, and materials.

G. Performance Data:

Medcomp has determined that no mandatory performance standards have been established for the proposed devices under Section 514 of the Medical Amendments to Federal Food, Drug, and Cosmetic Act or by any subsequent regulatory action.

Physical testing was performed on the Medcomp .010" Vascular Guidewires following the guidance of ISO 11070 and FDA's Coronary and Cerebrovascular Guidewire Guidance (1995) to assure design integrity and performance for the intended use.

Biocompatibility testing was conducted in accordance with ISO 10993 to confirm safety of the proposed device materials for use in an externally communicating device with limited indirect blood path contact.

H. Conclusion:

The proposed devices are similar to other devices currently on the market. The materials used in construction of the proposed devices are identical to those used in comparable legally-marketed devices and present no unusual or unacceptable risk to the patient. The optional hydrophilic and silicone coating materials and processes used on the proposed device are also used on legally marketed predicate devices.

No clinical studies were performed as part of the 510(k) process as the product is comparable to products currently cleared for marketing and can be applied under the substantial equivalence claim.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2009

Medical Components Inc.
c/o Ms. Lisa Weikert
Regulatory Specialist
1499 Delp Drive
Harleysville, PA 19438

Re: K081775
Trade/Device Name: Medcomp .010" Vascular Guidewires
Common Name: Catheter guide wire
Regulation Number: 21 CFR 870.1330
Regulatory Class: II
Product Code: DQX
Dated: February 26, 2009
Received: February 17, 2009

Dear Ms. Weikert:

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 such 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); good manufacturing practice requirements as set

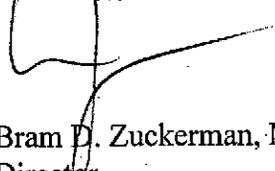
Page 2 - Ms. Lisa Weikert

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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

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): K081775

Device Name: Medcomp® .010" Vascular Guidewires

Indications for Use:

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This device is not intended for coronary or cerebrovascular use.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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 K081775