



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ameco Medical Industries
C/O Mr. Ray Kelly
RA/QA Specialist
Ray Kelly
79 Brookline Road
Mason, New Hampshire 03048

DEC 21 2011

Re: K110794

Trade/Device Name: Amecath CVC and Amecath Pressure CVC short term single and multi-lumen catheterization kits

Regulation Number: 21 CFR 880.5200

Regulation Name: Intravascular Catheter

Regulatory Class: Class II

Product Code: FOZ

Dated: December 15, 2011

Received: December 19, 2011

Dear Mr. Kelly:

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.

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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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



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Section 3

INDICATIONS FOR USE

510(k) Number (if known):

Device Name:

"Amecath CVC" and "Amecath Pressure CVC" short term single and multi-lumen catheterization kits

Indications For Use:

Indicated to permit short-term (<30 day) central venous access for the treatment of diseases or conditions requiring central venous access, including, but not limited to the following:

- Lack of usable peripheral IV sites
- Central venous pressure monitoring
- Total parenteral nutrition (TPN)
- Multiple infusions of fluids, medications, or chemotherapy
- Frequent blood sampling or receiving blood transfusions/blood products
- Infusions that are hypertonic, hyperosmolar, or infusions that have divergent pH values
- Injection of contrast media in pressure CVC only

When used for pressure injection of contrast media, do not exceed the maximum indicated flow rate for each catheter lumen. The maximum pressure of power injector equipment used with the pressure injectable CVC may not exceed 300psi.

Prescription Use ✓
(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)

 R. C. Chyan 12/21/14
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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