

A. 510(k) Summary

FEB 27 1998

510(k) SUMMARY

SUBMITTER: eMed Corp.
CONTACT PERSON: John Dockter
Senior Engineer
DATE PREPARED: April 25, 1997
TRADE NAME: Microfuse Membrane Infusion Catheter
CLASSIFICATION NAME
and NUMBER: Catheter, Infusion
21 CFR, 870.1250

PREDICATE DEVICES:

LocalMed - Kaplan-Simpson InfusaSleeve™ II Catheter, K933549
Scimed - Dispatch Catheter, K932616
Cardiovascular Dynamics Inc. (CDI)
BULLET™ Infusion Catheter, K931027

DEVICE DESCRIPTION:

The Microfuse Membrane Infusion Catheter is a non-dilatation, over-the-wire infusion device designed for localized delivery of solutions through a microporous membrane. The membrane gently "sweats" solution through its many pores. The device can accommodate a coronary guidewire.

INTENDED USE:

The Microfuse Membrane Infusion Catheter is intended for controlled and selective infusion of therapeutic agents into subselected region(s) within the coronary vasculature.

FUNCTIONAL & SAFETY TESTING:

Functional and safety testing consisted of examination and function of the device under conditions similar to those found in normal usage, and raise no new issues regarding safety and effectiveness of the device. Test requirements were set to ensure conformance to product specification.

CONCLUSION:

The Microfuse Membrane Infusion Catheter is substantially equivalent to the predicate devices based on the similarities in functional design, materials and indications for use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 1998

Mr. John Vanden Hoek
Director of Engineering
E-Med Corporation
651 Campus Drive
St. Paul, MN 55112

Re: K971619
Microfuse Membrane Infusion Catheter
Regulatory Class: II (two)
Product Code: 74 KRA
Dated: February 9, 1998
Received: February 11, 1998

Dear Mr. Hoek:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

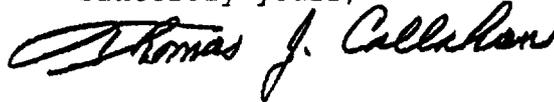
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation

Indications for Use

e Med's Microfuse Membrane Infusion Catheter is a nondilatation over-the-wire device intended for the localized infusion of therapeutic solution(s) in the coronary vasculature through a microporous membrane. The catheter is intended to be coaxially tracked over a guidewire to access a subselective infusion region in the coronary vasculature. The technique, rate of administration, duration of infusion, and appropriate sizing of the membrane to the arterial diameter is determined by the operating physician. The infusion solution should be used in accordance with the manufacturer's instructions for use.

Prescription Use ✓
(Per 21 CFR 801.109)

Christy M. J. Ba for TJC

(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K971619