K020530

APR 2 9 2002

**EXHIBIT 2**

Evans Medical, Inc.
295 Old Limekiln Road
Chalfont, PA 18914
Phone 215-249-4882
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Contact: Paul Lambert
January 7, 2002

## 510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: "Evans Sub-Q" (Catalog # MC4206) Winged Subcutaneous Tissue Infusion Set
   Classification Name: FPA
   Common/Usual Name: I.V. Administration Set

2. Equivalent legally marketed device: This device is similar in design and in function to the Minimed MMT-106. MMT-107, MMT-133, K961474.

3. Indications for Use (intended use): "Evans Sub-Q" (Catalog # MC4206) Winged Subcutaneous Infusion Set is intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe. (The device is supplied sterile, for single use only. It is a prescription device)

4. Description of the device: The device consists of a sterile packaged kit including the infusion set and an adhesive dressing to hold the device in place. The infusion set has a luer lock at one end and a 90 degree needle mounted to a butterfly stabilizer at the other end, connected by 42" of 2mm medical grade tubing. The luer lock connects to the infusion pump device. The device is for single use.

5. Safety and Effectiveness, comparison to predicate device:

| Comparison Areas | Minimed MMT-106. MMT-107, MMT-133, K961474; | "Evans Sub-Q" (Catalog # MC4206) Winged Subcutaneous Tissue Infusion Set |
|---|---|---|
| Indications for use | Intended to provide subcutaneous infusion of medicine from an external infusion pump | Intended to provide subcutaneous infusion of medicine from an external Infusion pump or syringe |
| Materials | Medical grade plastics and stainless steel needle | SAME |
| Packaging | Packed sterile for single patient use | SAME |

6. Testing information and Conclusion
   In all material respects, the "Evans Sub-Q" (Catalog # MC4206) Winged Subcutaneous Infusion Set is substantially equivalent to several similar devices already on the US market. Testing was performed according to internal company procedures. Test results support the conclusion that actual device performance satisfies the design intent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2002

Evans Medical, Incorporated
C/O Mr. Daniel Kamm
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K020530
Trade/Device Name: Evans SUB-Q ( Catalog MC4206) Winged Subcutaneous Tissue Infusion Set
Regulation Number: 880.5440
Regulation Name: I.V. Adminstration Set
Regulatory Class: II
Product Code: FPA
Dated: February 18, 2002
Received: February 19, 2002

Dear Mr. Kamm:

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 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020530

**j) Indications for Use**

510(k) Number K020530
"Evans Sub-Q" (Catalog # MC4206) Winged Subcutaneous Tissue Infusion Set is intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe. .

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020530