510(K) SUMMARY

K972135

AUG 26 1997

9.0 Summary of Safety and Effectiveness

9.1 Trade/Proprietary Name: Maersk Medical Pureline™ Comfort™ Subcutaneous Infusion Set

9.2 Common/Usual Name: Subcutaneous Infusion Set with indwelling catheter

9.3 *Classification Name:* *Intravascular Administration Set*

9.4 Substantial Equivalence: The modified Pureline™ Comfort™ Subcutaneous Infusion Sets are substantially equivalent to the currently marketed Pureline™ Comfort™ Subcutaneous Infusion Sets (K95018).

9.5 Device Description

The general description, operation, construction and use of the Maersk Medical Pureline™ Comfort™ Subcutaneous Infusion Sets With Indwelling Catheters has not changed as a result of the modifications. They remain sterile, non-pyrogenic, single use subcutaneous infusion sets designed to be used with commercially available infusion devices. The following discussion remains valid.

There are two basic components provided for each device. The first is a stand-alone subcutaneous indwelling catheter. This catheter is provided as an integral assembly with a Teflon cannula, adhesive backed fixation tape, an injection port and the female portion of a proprietary plastic "click-lock" connector. The catheter assembly comes with a stainless steel insertion cannula. The insertion cannula is mounted to a male portion of the proprietary plastic "click-lock" connector. The insertion cannula is come to the user inserted through the injection port and the inner lumen of the Teflon catheter with the needle end protruding past the tip of the catheter. The male connector is locked to the female connector on the indwelling catheter. A needle protector is assembled over the Teflon catheter and the insertion cannula. A separate male portion of the proprietary connector without the insertion cannula is provided in the package. This component is used to attach to the female connector of the catheter after the indwelling Teflon cannula has been inserted and the steel insertion cannula has been withdrawn. The connector protects the indwelling catheter when the infusion set is not attached.

The second component of the Maersk Medical Subcutaneous infusion Set with Indwelling Catheter is the infusion set. The infusion set is comprised of a co-extruded tube with a female luer lock connector at the pump end and a stainless steel needle incorporated into the male portion of the proprietary plastic "click-lock" connector at the patient end. In order to maintain the sterility of the infusion path, a male luer cap covers the female luer lock connector and the male "click-lock" connector comes attached to a mating female connector. The sets come packaged in blister packs sealed with paper lid stock.

9.6 Intended Use

The Intended Use for the device has not changed. The Maersk Medical Pureline™ Comfort™ Subcutaneous Infusion Sets with Indwelling Catheters continue to be intended for the infusion and/or injection of fluids into the body below the surface of the skin. The indwelling catheter can be inserted

independently from the infusion catheter and can be accessed for injections through the injection port. The indwelling catheter can also be securely attached to the infusion catheter by means of a proprietary "click-lock" connector for the infusion of drugs subcutaneously. The infusion set can be detached from the indwelling catheter, and the catheter capped, to allow freedom from the infusion set and pump for showers, athletics or other activities.

9.7 Technological Characteristics

The technological characteristics of the deice have not been affected by these modifications.

9.8 Performance Data

The results of the biocompatibility testing and component security testing showed the device is substantially equivalent to the unmodified device.

9.9 Conclusion

Based on the design equivalency and the functional and safety testing, Maersk Medical has determined that the Maersk Medical Pureline™ Comfort™ Indwelling Subcutaneous Catheter and Infusion Sets are substantially equivalent to the devices currently marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Lee Leichter
P/L Biomedical
7690 Cameron Circle
Fort Myers, Florida 33912

AUG 26 1997

Re: K972135
Trade Name: Maersk Medical Pureline Comfort Subcutaneous Infusion Set
Regulatory Class: II
Product Code: FPA
Dated: May 14, 1997
Received: June 6, 1997

Dear Mr. Leichter:

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 (Premarket 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 requirement, 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 premarket 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.

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) 594-4618. 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" (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,

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

Enclosure

INDICATIONS FOR USE

510(k) File Number:

Device Name: Maersk Medical Pureline™ Comfort™ (Disetronic Tender™) Subcutaneous Infusion Set

Indications For Use: The Subcutaneous Infusion Sets with Indwelling Catheters are indicated for the infusion and/or injection of fluids into the body below the surface of the skin.

(Division Sign-Off) Catherine C. Cavanaugh
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972135

Prescription Use ✓
(Per 21 CFR 801.109)