K060339

510(k) Summary

In accordance with section 513(I) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

Tyco Healthcare/Kendall
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: February 08, 2006

APR 28 2006

1. Contact Person

Bridget Gardner
Manager, Regulatory Affairs
(508) 261-6384

2. Name of Medical Device

Classification Name:	Catheter, Intravascular, Therapeutic, Short-Term
Common or Usual Name:	Kendall Monoject PreFill™ ADVANCED™ 0.9%Sodium Chloride Flush Syringes for Sterile Delivery

3. Identification of Legally Marketed Device

The proposed Kendall Monoject PreFill™ ADVANCED™ 0.9%Sodium Chloride Flush Syringes for Sterile Delivery is substantially equivalent in intended use, function and composition to the currently marketed Kendall Monoject PreFill™ ADVANCED™ 0.9% Sodium Chloride Flush Syringes K032438.

4. Device Description

The proposed device is an extension to the Kendall Monoject PreFill™ ADVANCED™ Flush Syringe line is to include one or more PreFill syringe configurations equivalent to those already marketed by Tyco Healthcare with the syringe delivered to the customer in a package that will maintain the sterility of the syringe exterior surface.

5. Device Intended Use

Kendall Monoject PreFill™ ADVANCED™ 0.9%Sodium Chloride Flush Syringes for Sterile Delivery is indicated for use in flushing compatible intravenous administration sets and indwelling intravascular access devices.

6. Product Comparison

The proposed device has the same technological characteristics as the predicate devices. Each consists of Monoject® plastic syringes containing 0.9% Sodium Chloride.

7. Nonclinical Testing

Biocompatibility testing of the proposed device has demonstrated that it meets the requirements of guidelines presented in the 10993 ISO Standard, Part 1 and with the FDA modified matrix presented in memorandum G95-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Bridget Gardner
Manager, Regulatory Affairs
Tyco Healthcare Kendall
15 Hampshire Street
Mansfield, Massachusetts 02048

APR 28 2006

Re: K060339
Trade/Device Name: Kendall Monoject PreFill™ ADVANCED™ 0.9%Sodium Chloride Flush Syringes for Sterile Delivery
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: NGT
Dated: April 13, 2006
Received: April 14, 2006

Dear Ms. Gardner:

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). please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital.
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060339

Device Name: Kendall Monoject PreFill™ ADVANCED™ 0.9%Sodium Chloride Flush Syringes for Sterile Delivery

Indications for Use: Kendall Monoject PreFill™ ADVANCED™ 0.9%Sodium Chloride Flush Syringes for Sterile Delivery is indicated for use in flushing compatible intravenous administration sets and indwelling intravascular access devices.

Prescription Use _v___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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