K032438

JUN 3 0 2004

EXHIBIT # 7

Page 1 of 2

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:

The Kendall Company
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: August 4, 2003

1. Contact Person

David A. Olson
Vice President, Regulatory Affairs
(508) 261-8530

2. Name of Medical Device

Classification Name: Catheter, Intravascular, Therapeutic, Short-Term

Common or Usual Name: Monoject® Prefill Flush Syringes

3. Identification of Legally Marketed Device

The proposed Kendall Monoject® Prefill Flush Syringes are substantially equivalent in intended use, function and composition to the currently marketed Monoject PreFill Sodium Chloride and Heparin Lock Flush Syringes, 510(k) numbers K011283 and K013556.

4. Device Description

The proposed device is a sterile, single use, standard piston syringe of various sizes and fill volumes containing either 10 or 100 USP Heparin units/ml, or, 0.9% Sodium Chloride USP.

5. Device Intended Use

The proposed device is indicated for use in flushing compatible intravenous tubing systems and indwelling intravascular access devices.

6. Product Comparison

The proposed device has the same technological characteristics and indications for use as the predicate devices. The proposed modification involves a change in the manufacturing process.

7. Nonclinical Testing

Verification testing for the proposed change involved microbiological, physical, functional and product stability testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2004

Tyco Healthcare
Mr. David A. Olson
Vice President, Regulatory Affairs
Kendall
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K032438
Trade/Device Name: Monoject 0.9% Sodium Chloride and Heparin Lock Flush Syringe
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: NGT
Dated: April 29, 2004
Received: May 3, 2004

Dear Mr. Olson:

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.

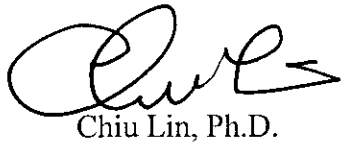
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618. 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/dsma/dsmamain.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 Statement

510(k) Number (if known):

Device Name: Monoject 0.9% Sodium Chloride and Heparin Lock Flush Syringe

Indications for Use: The 0.9% Sodium Chloride Flush Syringe is indicated for use in flushing compatible intravenous tubing systems and indwelling intravascular access devices.

The Heparin Lock Flush Syringe, 10 and 100 units/ml is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices.

Please Do Not Write Below This Line – Continue On Another Page If Needed

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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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032438