K991758

ATTACHMENT 7

510K SUMMARY

Contact Person:
Frank J. Fucile, Vice President, Regulatory Affairs
The Kendall Company
15 Hampshire Street, Mansfield, MA 02048
Phone: (508) 261-8532
Date Prepared: May 19, 1999

Device:

Brand Name:	Monoject Insulin Syringes
FDA Classification Name:	Piston Syringe, per 21 CFR 880.5860
Common or Usual Name:	Insulin Syringe

Predicate Devices: Monoject Insulin Syringes are substantially equivalent in intended use, function and composition to Monoject Insulin Syringe, 510K #s K851090 and K922522 and B-D Insulin Syringes, 510K #s K955235 and K980580.

Device Description/Intended Use: Monoject Insulin Syringes are used for subcutaneous injection of U-100 Insulin. These devices are sterile, single use, disposable hypodermic syringes with permanently affixed hypodermic needles. Monoject Insulin Syringes consist of a syringe barrel, a plunger rod, and a hypodermic needle permanently affixed to the tip of the syringe with epoxy. Monoject Insulin Syringes are available in 1.0 cc (100 units), 0.5 cc (50 Units) and 0.3 cc (30 units) syringe capacities with the following sizes of hypodermic needle: 28 GA x ½ inch, 29 GA x ½ inch and 30 GA x 5/16 inch.

Summary of Technological Characteristics: The only design change being incorporated into current Monoject Insulin Syringes compared to currently marketed Monoject Insulin Syringes is the addition of a new needle size – 30 Gage x 5/16" Length. This needle is shorter and of smaller diameter than the current Monoject 29 Gage x ½" Length insulin needle. All other aspects are identical to current Monoject Insulin Syringes. Monoject Insulin Syringes conform to International Standard ISO 8537:1991(E) "Sterile single-use syringes, with or without needle, for insulin", except in regard to the presence of the 30 gage (0.30 mm OD.) needle which is not contained in the standard and in regard to certain marking requirements.

The new Monoject 30 Gage x 5/16" insulin needle is identical in materials, design and intended use to 30 Gage x 5/16" insulin needles currently marketed by Becton-Dickinson.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 1999

Mr. Frank J. Fucile
Vice President, Regulatory Affairs
The Kendall Company
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K991758
Trade Name: Monoject® Insulin Syringe
Regulatory Class: II
Product Code: FMF
Dated: May 19, 1999
Received: May 24, 1999

Dear Mr. Fucile:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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

ATTACHMENT 8

INDICATIONS FOR USE STATEMENT

510K Number:

Device Name: MONOJECT Insulin Syringes

Indications for Use: MONOJECT Insulin Syringes are used for subcutaneous injection of U-100 Insulin.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use ✓
(per 21 CFR 801.109)

Patricia Cuccinotta

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K991758