JUN 14 1999

K984576

II. 510(k) Summary as required by 807.95 (c)
SUMMARY AND CERTIFICATION
Summary of Safety & Effectiveness Information

II.1. Proprietary Device Name

K-Pack II Needle

II.2. Classification Name

Hypodermic Single Lumen Needle

II.3. Reason for submission

New Device

II.4. Intended Use

The K-Pack II Needle being a Hypodermic Single Lumen Needle is a sterile medical device for single use, intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

II.5. Description

The K-Pack II Needle is a sterile hypodermic single lumen needle, for single use consisting of a stainless steel tube that is sharpened at one end and at the other end joined to a female luer connector (hub) made of polypropylene designed to be connected with a male connector (nozzle) of a piston syringe or an intravascular administration set.

II.6. Substantial Equivalence

The K-Pack II Needles submitted in this 510k file are substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Terumo Disposable Hypodermic Needle which is the subject of K771203. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

INTENDED USE:	Both needles being Hypodermic Single Lumen Needles are sterile medical devices for single use, intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.
DESIGN AND MATERIALS:	Both needles are made of a stainless steel needle tube that is sharpened at one end (both types of needles having exactly the same geometry) and at the other end joined to a female connector (6% luer) made of polypropylene. The difference between both needles is the packaging style and the sterilization method.

K-Pack II needles are packed in a hard pack (cap - case) and sterilised by ethylene oxide while the Terumo Needles are packed in a blister pack (film – film) and sterilized by gamma-irradiation.
The differences in packaging style and sterilization method do not affect the substantial equivalence of the devices.

Proposed:

PRODUCT CODE	NEEDLE GAUGE	NEEDLE LENGTH	NEEDLE BEVEL
KN-2325RB	23	1"	regular
KN-2525RB	25	1"	regular
KN-2516RB04	25	5/8"	regular

Predicate:

PRODUCT CODE	NEEDLE GAUGE	NEEDLE LENGTH	NEEDLE BEVEL
3NN*2325R	23	1"	regular
3NN*2525R	25	1"	regular
3NN*2516R	25	5/8"	regular

Materials:

COMPONENT	PROPOSED	PREDICATE
Cannula	Stainless steel	Stainless steel
Hub	Polypropylene	Polypropylene
Glue	Epoxy glue	Epoxy glue
Lubricant	Silicone	Silicone

PRINCIPLES OF OPERATION/ TECHNOLOGY STATEMENT

The K-Pack II Needle and the Terumo Disposable Hypodermic Needle are both operated manually.

COMPARISON TESTING OF K-PACK NEEDLES WITH EN ISO 7864

The K-Pack II Needles comply with the requirements specified in EN ISO 7864 (1995) Sterile Hypodermic Needles for single use (= ISO 7864: 1993) with exception of Section 9.1 Conical fitting: if the hub has a locking fitting, it shall be in accordance with ISO 594-2.
The K-Pack II Needles are not completely matching the specification of ISO 594-2, however when tested in accordance to ISO 594-2, no liquid or air leakage is observed.

Comment:
Section 13.2 Patency of lumen: no specifications are given for a 25G having an ultra thin wall needle.
Consequently the 25G K-Pack Needle having an ultra thin wall needle could not be compared with a reference for this property.

II.8. Additional Safety Information

The sterility of the K-Pack II Needles is assured by using a validated sterilization method qualified in accordance with EN 550: "Sterilization of Medical Devices: Validation and routine control of ethylene oxide" to a sterility assurance level (SAL) of 10^{-6} as required by EN 556: "Sterilization of Medical Devices: Requirements for medical devices to be labelled STERILE."

In routine the sterilization of each lot is assured by checking the recordings of the physical parameters and by performing a sterility control on biological indicators placed at different places in the sterilization tank and sterilized simultaneously with the products.

The biocompatibility of the K-Pack II Needles is tested in accordance with the tests recommended in the FDA General Program Memorandum # G95-1 (5/1/95): Use of International Standard ISO 10993 "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing:" [External Communicating Devices, Blood Path Indirect, Limited Duration of Contact (L 24 hours)].
The blood contacting materials were found to be compatible.

A LAL test is performed on production samples of each lot number.

The manufacturing control test methods include controls on functional performance.

The expiration dating for the K-Pack II Needles has been established to be 60 months or five (5) years.

II.9. Conclusion

The K-Pack II Needles submitted in this 510k file are substantially equivalent in intended use, design, specifications, technology/principles of operations, materials and performance to the cleared Terumo Disposable Hypodermic Needle which is subject of K771203.
Differences between the devices cited in this section do not raise any new issues of safety on effectiveness.

II.10. Preparation info

Date prepared: 03/12/1998
Prepared by: M.J. Aerts - Manager Regulatory Affairs
Prepared for: TERUMO EUROPE N.V.
Researchpark Zone 2, Interleuvenlaan 40, 3001 Leuven
BELGIUM
Tel.: 0032 / 16 / 381 353

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 1999

Mrs. M.J. Aerts
Manager
Regulatory Affairs
TERUMO EUROPE NV
Researchpark Zone 2 Haasrode
Interleuvenlaan 40
B-3001 Leuven - Belgie (Belgium)

Re: K984576
Trade Name: K-Pack II (Hypodermic Needle) 23G X 1, Model KN-2325RB
Regulatory Class: II
Product Code: FMI
Dated: May 11, 1999
Received: May 14, 1999

Dear Mrs. Aerts:

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

510(k) Number (if known): K984576

Device Name: K-PACK II NEEDLE (= Hypodermic Needle)

Indications For Use:

The K-Pack II Needle being a Hypodermic Single Lumen Needle is a sterile medical device for single use. intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cusenta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984576

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)