K110850

510(k) SUMMARY as required by 807.92
Summary of Safety & Effectiveness Information

JUN - 9 2011

Submitter information

Prepared for:	**TERUMO EUROPE N.V.** **Interleuvenlaan 40,** **3001 Leuven,** **BELGIUM**
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Date prepared:	**March 2011**

II.1. Device Name

Proprietary Name

K-Pack II Needle - 27G & 30G Thin Wall

Classification Name

Hypodermic Single Lumen Needle

21CFR, Section 880.5570

Classification: Class II

II.2. Reason for Submission

This 510k is being submitted to extend the cleared K-Pack II Needle (K984576) product line.

The cannula wall of these 27G & 30G needles is thinner than what is currently cleared under the 510k K984576 and 510k K001572 for the 27 Gauge needle and under the 510k K062608 for the 30 Gauge needle.

Please note that the 27 Gauge needle size was added to 510k K984576 through internal documentation as specified under 510(k) Memorandum #K97-1 "Deciding When to Submit a 510(k) for a Change to an Existing Device". It was concluded that the addition of the 27 Gauge size did not significantly affect the safety or effectiveness of the device and therefore no 510(k) was submitted.

The 30G Thin Wall K-Pack II Needle can also be packaged in a short case instead of a long one as cleared under 510k K062608.

The thinner needle and the shorter case were cleared for a 29 Gauge needle under the 510k K082820 and the shorter case was cleared for the 27 Gauge needle under the 510k K984576 (internal documentation).

This Special 510k is therefore being submitted due to potential issues of safety and effectiveness specific for a thinner wall needle for the 27 and 30 Gauge needle.

This 510k will provide supporting information that the 27G & 30G Thin Wall K-Pack II Needles are safe and effective and an acceptable extension of the current K-Pack II Needle product line.

II.3. Intended Use

The 27G & 30G Thin Wall K-Pack II 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.

Note: This is the same intended use as the predicate devices, K-Pack II Needle - K984576, Neolus Needle - K001572, 29G & 30G K-Pack II Needle – K062608 and 29G K-Pack II Needle Thin Wall - K082820.

II.4. Description

The 27G & 30G Thin Wall K-Pack II Needles are sterile hypodermic single lumen needles, 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.

II.5. Substantial Equivalence

The 27G & 30G Thin Wall K-Pack II Needles are substantially equivalent in intended use, design, technology/principal of operation, materials, and performance to the following cleared devices:

1. K-Pack II Needles (K984576)
2. Neolus Needles (K001572)
3. 29 Gauge & 30 Gauge K- Pack II Needles (K062608)
4. 29 Gauge K-Pack II Needle Thin Wall (K082820)

Differences between the devices do not raise any significant issues of safety and effectiveness.

II.6. Summary of Verification Activities

All necessary verification and validation tests have been performed by testing the 27G & 30G Thin Wall K-Pack II Needles in accordance with EN ISO 7864 (1995). Summary of the verification activities including acceptance criteria is given in the table below:

TEST	ACCEPTANCE CRITERIA
1. Cleanliness	Inspected by normal or corrected-to-normal vision without magnification under an illuminance of 300 lx, the surface of the hypodermic needle tube shall appear free from particles and extraneous matter. When examined under x2.5 magnification, the hub socket shall appear free from particles and extraneous matter.
2. Limits for acidity or alkalinity	Δ pH for K-Pack Needles extract solution is within 1 unit of the control fluid.
3. Limits for extractable metals	The extract solution of the 27G & 30G Thin Wall K-Pack II Needles has a content of extractable metals which is, when corrected for the metal content of the control fluid: Σ Pb, Sn, Zn, Fe ≤ 5 mg/l Cd < 0. 1 mg/l
4. Size designation	Outside diameter and nominal length are expressed in mm (and G x ")
5. Colour coding	Hub and label are colour coded following ISO 6009
6. Conical fitting	6% luer taper, compliant with requirements of ISO 594-1 and ISO 594-2
7. Effective needle length	The effective length = nominal length + 1 mm/-2 mm
8. Lubricant	Needles are uniformly lubricated and the silicone is not visible as droplets on the outside surface of the needle, the quantity will not exceed 0.25 mg/cm^2
9. Needle point	The needle point of the 27G & 30G Thin Wall K-Pack II Needles is in the center of the bevel, is sharp and is free from extraneous matter, burr, edges and hooks.
10. Bonding strength between hub and cannula	The bonding strength between hub and cannula is ≥ 22N.
11. Patency of lumen	27G: A stylet with a diameter of 0.19 mm is passing through the needle. 30G: A stylet with a diameter of 0.13 mm is passing through the needle.
12. Flow rate	27G: ≥ 2.72 and ≤ 4.25 ml/min 30G: ≥ 0.73 and ≤1.14 ml/min

II.7. Additional Safety Information

The sterility of the 27G & 30G Thin Wall K-Pack II Needles is assured by using a validated sterilization method qualified in accordance with EN ISO 11135: "Medical Devices: Validation and routine control of ethylene oxide sterilization" to a sterility assurance level (SAL) of 10^{-6} as required by EN 556-1: "Sterilization of Medical Devices - Requirements for medical devices to be designated "STERILE" - Part - 1: Requirements for terminally sterilized medical devices".

Ethylene oxide residual levels resulting from EtO sterilization are in compliance with EN ISO 10993-7: "Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals"

The 27G & 30G Thin Wall K-Pack II Needle, like the standard K-Pack II Needle (K984576), is an Externally Communicating device, Contacting Circulating Blood, Limited Exposure (≤ 24 hrs). The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part-1: Evaluation and testing".

The expiration dating for the 27G & 30G Thin Wall K-Pack II Needles has been established at 5 years which is the same as the cleared K-Pack II Needles.

II.8. Conclusion

In summary, the 27G & 30G Thin Wall K-Pack II Needles are substantially equivalent in intended use, design, technology/principal of operation, materials, and performance to the following cleared devices:

1. K-Pack II Needles (K984576)
2. Neolus Needles (K001572)
3. 29 Gauge & 30 Gauge K- Pack II Needles (K062608)
4. 29 Gauge K-Pack II Needle Thin Wall (K082820)

Differences between the devices do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JUN - 9 2011

Re: K110850
Trade/Device Name: K-Park II Needle-27G & 30G Thin Wall
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: May26, 2011
Received: May 27, 2011

Dear Mrs. Aerts:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: K-Pack II Needle - 27G & 30G Thin Wall

Indication For Use:

The 27G & 30G Thin Wall 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.

Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Acting for Richard Chapman

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110850