K110527

JUN - 6 2011

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

Submitter information

Prepared for: TERUMO EUROPE N.V.
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Date prepared: February 2011

II.1. Device Name

Proprietary Name

K-Pack Surshield™ Needle

Classification Name

Hypodermic Single Lumen Needle

21CFR, Section 880.5570

Classification: Class II

II.2. Reason for Submission

New Device

II.3. Intended Use

The K-Pack Surshield™ Needle is a sterile hypodermic needle for single use with a passive sharps protection feature that covers the cannula immediately and permanently after use; and is intended for use in combination with hypodermic syringes for subcutaneous and intramuscular injection as well as for injection in infusion lines.

II.4. Description

The 25G K-Pack Surshield™ Needle is a 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. Furthermore the needle has a passive sharps protection feature that covers the cannula immediately and permanently after use. The K-Pack Surshield™ Needle is packed in a hard pack (cap - case) which is sealed with a perforated self-adhesive paper label.

II.5. Substantial Equivalence

The "K-Pack Surshield™ Needle", manufactured by Terumo Europe N.V., submitted in this 510(k) file is substantially equivalent in intended use, description/specifications, technology/principles of operation, materials and performance to the following cleared devices:

1. NovoFine® Autocover® 30G x 8 mm (K050106) manufactured by Novo Nordisk inc., used as predicate for the sharps protection feature.
2. Terumo Surguard®2 Safety Needle (K051865) manufactured by Terumo Philippines Corporation, used as predicate for the functionality of the needle.
   The difference between this predicate and the proposed device is that the proposed device contains a passive sharps protection feature while the predicate contains an active sharps protection feature.

Any 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 K-Pack Surhield™ Needle 25G x 5/8" – 0.5 x 16 mm in accordance with EN ISO 7864 (1995) and ISO/FDIS 23908 (2010). 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 K-Pack Surshield 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 K-Pack Surshield Needles is in the center of the bevel, is sharp and is free from extraneous matter, burr, edges and hooks.

TEST	ACCEPTANCE CRITERIA
10. Bonding strength between hub and cannula	The bonding strength between hub and cannula for this K-Pack Surshield Needle is $\geq$ 22N.
11. Patency of lumen	A stylet with a diameter of 0.23 mm is passing through the needle.
12. Flow rate	The flow rate for this needle is 3.0 ml/min.
13. Visual marking indicating status of safety feature	Visual indication : Light blue = Ready for use No colour = Shield already locked
14. Forces for activating the sharps injury protection feature	The force to activate the safety feature of the device is maximum 2.16 N. The force during use of the device is maximum 3.20 N.
15. Forces for challenging the safety feature	Once in the safe mode, the safety feature shall withstand 10 cycles of a minimum overriding force of 80 N.
16. Challenging the safety feature once in safe mode	Once in safe mode, the cannula tip cannot be accessed when the device is stressed during a 10 cycle procedure of minimum 80 N compressive load.

II.7. Additional Safety Information

The sterility of the K-Pack Surshield™ Needle is assured by using a validated sterilization method qualified in accordance with EN ISO 11135-1:2007 "*Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*" 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 K-Pack Surshield™ Needle is an External Communicating Device, that can contact tissue, bone or dentine or that can indirectly contact the blood path, Limited Exposure (≤ 24 hrs). The devices' 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, "Biological Evaluation of Medical Devices Part-1: Evaluation and testing".

The expiration dating for the K-Pack Surshield™ Needle has been established at 5 years.

II.8. Conclusion

The K-Pack Surshield™ Needle manufactured by Terumo Europe N.V. and submitted in this 51(k) file is substantially equivalent in intended use, description, specifications, and technology/principles of operation, materials and performance to the following cleared devices:

1. NovoFine® Autocover® 30G x 8 mm (K050106) manufactured by Novo Nordisk inc., which is used as predicate for the sharps protection feature.
2. Terumo Surguard®2 Safety Needle (K051865) manufactured by Terumo Philippines Corporation, which is used as predicate for the functionality of the needle.
   The difference between this predicate and the proposed device is that the proposed device contains a passive sharps protection feature and the predicate an active sharps protection feature.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. M.J. Aerts
Regulatory Affairs Manager
Terumo Europe N.V.
Interleuvenlaan 40
Leuven, Belgium 3001

Re: K110527
Trade/Device Name: K-Pack Surshield™ Needle, Hypodermic Needle for Single Use
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: May 2, 2011
Received: May 6, 2011

JUN - 6 2011

Dear Ms. 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,

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 Surshield™ Needle

Indication For Use:

The K-Pack Surshield™ Needle is a sterile hypodermic needle for single use with a passive sharps protection feature that covers the cannula immediately and permanently after use; and is intended for use in combination with hypodermic syringes for subcutaneous and intramuscular injection as well as for injection in infusion lines.

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

Richard C. Chapman 6/2/11

Division Sign-Off)
)ivision of Anesthesiology, General Hospital
.nfection Control, Dental Devices

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