

1082820

OCT 23 2008

510(k) SUMMARY

Prepared for: TERUMO EUROPE N.V.
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Date prepared: September 2008

Note: Class III Summary & Certification is not applicable for the submission of a Class II device

II. 510(k) SUMMARY

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

II.1. Device Name

Proprietary Name

K-Pack II Needle - 29G 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 this 29G needle is thinner than what is currently cleared under the K-Pack II Needle 510k (K062608) for the 29 Gauge needle. In addition, the 29G Thin Wall K-Pack II Needle is packaged in a short case instead of a long one as cleared in K062608. This Special 510k is therefore being submitted due to potential issues of safety and effectiveness specific for a thinner needle and the shorter case. This 510k will provide supporting information that the 29G Thin Wall K-Pack II Needle is safe and effective and an acceptable extension of the current K-Pack II Needle product line.

II.3. Intended Use

The 29G 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.

Note: This is the same intended use as the predicate device, K-Pack II Needle – K984576 and 29 Gauge & 30 Gauge K- Pack II Needles (K062608)

II.4. Description

The 29G Thin Wall 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.

II.5. Substantial Equivalence

The 29G Thin Wall K-Pack II Needle is 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. 29 Gauge & 30 Gauge K- Pack II Needles (K062608)

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

II.6. Additional Safety Information

The sterility of 29G Thin Wall K-Pack II Needle 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" and 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" and EN 556-1/AC (2006).

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 29G 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 29G Thin Wall K-Pack II Needle has been established at 5 years which is the same as the cleared K-Pack II Needles.

II.7. Conclusion

In summary, the 29G Thin Wall K-Pack II Needle is 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. 29 Gauge & 30 Gauge K- Pack II Needles (K062608)

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mrs. MJ Aerts
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Interleuvenlaan 40
Researchpark Zone 2
Leuven, Belgium 3001

OCT 23 2008

Re: K082820

Trade/Device Name: K-Pack II Needle – 29G Thin Wall (hypodermic needle)
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: September 18, 2008
Received: September 25, 2008

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.

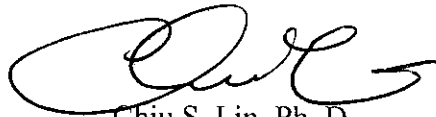
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu S. Lin, Ph. D
Division 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 - 29G Thin Wall (hypodermic needle)

Indication For Use:

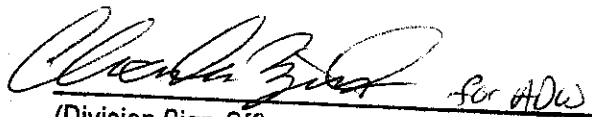
The 29G Thin Wall K-Pack II Needle being a Hypodermic Single Lumen Needle is a sterile medical device for single use, intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

Prescription Use X
(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)

 *Cheryl Zuercher* for ADW

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

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