K012646

AUG 2 7 2001

SUMMARY OF SAFETY & EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

A. Device Name

Proprietary Device Name: TERUMO® 30 Gauge Hypodermic Needle

Classification Name: Needle, Hypodermic, Single Lumen

B. Reason for Submission:

This 510k is being submitted to extend the cleared Terumo Hypodermic Needle* (K771203) product line. (*also referred to as the *standard Terumo needle*.) The size of the 30g needle is smaller than what is currently cleared under the current Hypodermic needle 510k (K771203). This Special 510k is being submitted because of potential issues of safety and effectiveness specific for a smaller/thinner needles. This 510k will provide supporting information that Terumo's 30 Gauge hypodermic needle is safe and effective and an acceptable extension of the current hypodermic needle product line.

C. Intended Use:

The TERUMO® 30 gauge hypodermic needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. It is intended to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set.

Note: This is the same intended use as the predicate device, Terumo Hypodermic Needle - K771203.

D. Description

The TERUMO® 30 Gauge hypodermic needle is comprised of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set.

E. Substantial Equivalence

The TERUMO® 30Gauge Hypodermic Needle is substantially equivalent in intended use, design, technology/principals of operation, materials, and performance to both the following cleared devices:

1. TERUMO® Hypodermic Needle (K771203)
2. BD 30 Gauge (Precision Glide) Hypodermic Needle *Pre-amendment

Unable to identify the 510(k) number for this device through published resources. It is believed to be a pre-amendment device although this could not be confirmed.

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

F. Principals of Operation/Technology

The TERUMO® 30Gauge Hypodermic Needle, Terumo Hypodermic needle (K771203), and BD 30G Precision Glide Hypodermic Needle (Pre-amendment) are all operated manually.

G. Materials

The TERUMO® 30Gauge Hypodermic Needle, standard Terumo needle, and BD 30G Precision Glide Hypodermic Needle are all comprised of stainless steel tubing attached to a plastic hub by means of an adhesive. The materials used in the proposed 30G needle and the cleared Terumo needle are the same.

H. Specifications

Product Code	Gauge Size	Needle Length	Hub Color*
NN3013R	30g	½"	Yellow

*Per ISO 6009

I. Performance

The following performance tests were performed on the Terumo 30g Hypodermic Needle:

- Cannula Adhesion
- Protector Fit
- Needle Penetration Force
- Leakage
- Blocked Cannula

None of the data raises any new issues of safety and effectiveness. Additionally, a risk analysis was conduct and there were no risks identified that warranted any design changes.

J. Additional Safety Information

a. Sterilization

Sterilization conditions have been validated in accordance with ANSI/AAMI/ISO 11137-1994 Medical Devices – Validation and Routine Control of Radiation Sterilization. This device is sterilized to a Sterility Assurance Level (SAL) of 10^{-6}.

b. Biocompatibility Testing

The TERUMO® 30Gauge Hypodermic Needle, like the standard Terumo Hypodermic needle K771203, is an Externally Communicating device, Circulating Blood, Limited Exposure (24 hrs). Blood contacting materials have been tested in accordance with 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 yellow colorant is the same colorant used in the cleared Terumo 20g Hypodermic Needle.) The needle in this 510k uses the same materials and method of sterilization as the standard Terumo Hypodermic needle, which has shown to be biocompatible. Therefore, no further testing was deemed necessary.

c. Expiration Dating

Expiration Dating for the Terumo 30g Hypodermic Needle will be 60 months (5 years) which is the same as the standard Terumo needle.

d. Pyrogen Testing

Pyrogen testing is performed in accordance with the requirements of the US Pharmacopoeia XXIII. Additionally, each lot is tested for the absence of endotoxins using the Limulus Amebocyte Lysate (LAL) gel clot test.

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K. Conclusion

In summary, the TERUMO® 30Gauge Hypodermic Needle is substantially equivalent in intended use, design, technology/principals of operation, materials, and performance to both the following cleared devices:

1. TERUMO® Hypodermic Needle (K771203)
2. BD 30 Gauge (Precision Glide) Hypodermic Needle (Pre-amendment)

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

Terumo's statement that this device is substantially equivalent to any other device is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended whatsoever to be the basis for a patent infringement action.

Date Prepared: July 31, 2001

Prepared by: Barbara Smith
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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) 594-4588. 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K012593

Device Name:
VITROS Chemistry Products Magnetic HDL-Cholesterol Reagent
VITROS CHOL Slide
VITROS Chemistry Products Calibrator Kit 2

Intended Use:
For in vitro diagnostic use only.
The VITROS Magnetic HDL-Cholesterol Reagent and VITROS CHOL Slides quantitatively measure HDL cholesterol (HDLC) concentration in serum and plasma.

VITROS Calibrator Kit 2
For in vitro diagnostic use only.
VITROS Calibrator Kit 2 is intended for use in calibration of the VITROS Chemistry Systems for the quantitative measurement of CHOL, Cl-, ECO2, HDLC, K+, Na+, and TRIG.

Summary and Explanation of Test:
HDL cholesterol is used to evaluate the risk of developing coronary heart disease (CHD). The risk of CHD increases with lower HDL cholesterol concentrations.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Kevin Alexander for Joan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012593

510(k) Number (if known): K012646

Device Name: TERUMO® 30 Gauge Hypodermic Needle

Indications For Use:

The TERUMO® 30 gauge hypodermic needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. It is intended to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set.

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(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012646