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Section H - 510(k) Summary

Date Summary Was Prepared: September 17, 2007

NOV 2 1 2007

Contact Person: Debora Stapleton
Regulatory Affairs
Covidien LP (formerly registered as Tyco Healthcare Group LP)
15 Hampshire Street
Mansfield, MA 02048
Telephone: 508-452-4866
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Device Trade Name: MONOJECT® 30 Gauge Hypodermic Needles, Regular and Thin Wall

Device Common Name: Needle, Hypodermic, Single Lumen

FDA Product Code: FMI, 21 CFR 880.5570

Classification Panel: General Hospital

Legally Marketed Devices to Which Substantial Equivalence Is Claimed:

- MONOJECT® Sterile M250 Hypodermic Needles, K854547
- TERUMO® 30 Gauge Hypodermic Needle, K012646

Device Intended Use: The proposed devices are intended for the injection of medications into or the withdrawal of body fluids from parts of the body below the surface of the skin.

Device Description: The devices consist 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.

Summary of Technological Characteristics: The proposed single use, disposable devices have the same technological characteristics as the predicate devices. The devices conform to FDA recognized safety and performance consensus standards for needles, including ISO 7864, ISO 9626, ISO 594-1, ISO 594-2, and ISO 6009.

The MONOJECT® 30 Gauge hypodermic needles with lengths ranging from 5/16" to 1-1/2" are of the same design and intended use to that of the predicate devices. They are meant as an extension to the MONOJECT® needle product line.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1 2007

Ms. Debora Stapleton
Senior Regulatory Affairs Specialist
Covidien LP
15 Hampshire Street
Mansfield, Masachusett 02048

Re: K073122
Trade/Device Name: 30 Gauge MONOJECT® Hypodermic Needles, Regular and Thin Wall
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: October 31, 2007
Received: November 6, 2007

Dear Ms. Stapleton:

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.

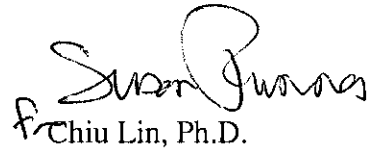
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073122

Device Name: 30 Gauge MONOJECT® Hypodermic Needles, Regular and Thin Wall

Indications For Use:

These devices are intended for the injection of medications into or the withdrawal of body fluids from parts of the body below the surface of the skin.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K073122