K040710 1 of 2

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SUMMARY OF SAFETY AND EFFECTIVENESS
TEGO
(NEEDLE- FREE ACCESS DEVICE)

§807.92(a)(1)

Contact Person	Dale Fairchild Regulatory Manager
Date of Summary Preparation:	August 10, 2004

§807.92(a)(2)

Trade Name:	TEGO
Common Name:	Needle-Free Access Device
Classification Name:	Intravascular administration set (21 CFR 880.5440

§807.92(a)(3)

Legally Marketed Substantially Equivalent Devices:	CLC 2000 Ultra-Site Valve

§807.92(a)(4)

Description of Device:	The TEGO is a one piece,swab-able, needle-free catheter patency device. The TEGO is intended for the capping of venous and arterial access devices. The TEGO has a low deadspace, a straight fluid path, high flow rate and an aesthetically and ergonomically pleasing profile. When a fluid

adminstration device is removed from the TEGO an automatic positive displacement of fluid will exit the device and prevent blood reflux.
The TEGO will permit the use of normal saline for what is known as a rountine flush and patency maintenance of the venous or arterial access device.
The materials include polycarbonate, silicone rubber, polyethlene and trace amounts of silicone as a lubricant. All of these materials are typically used in medical devices.

§807.92(a)(5)

Intended Use:

The TEGO is intended for use as an accessory to a vascular access device (catheter) used in Hemodialysis or as an accessory to an Intravascular Adminstration Set for the adminstration of fluids or withdraw of fluids from a patient through a cannula or needle placed in the vein or artery. The Gumby is a needle-free, closed capping device which will prevent blood loss or air entrainment through the catheter.The TEGO will permit access to the catheter without the use of needles and therefore passively aid in the reduction of needlestick injuries.

§807.92(a)(6)

Comparison of Technical Characteristics:

The TEGO is similar to legally marketed devices with the same intended use and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2004

Mr. Dale Fairchild
Regulatory Affairs Manager
ICU Medical, Incorporated
951 Calle Amanecer
San Clemente, California 92673

Re: K040710
Trade/Device Name: TEGO™ Needle Free Access Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administrative Set
Regulatory Class: II
Product Code: FPA
Dated: June 24, 2004
Received: June 25, 2004

Dear Mr. Fairchild:

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 (301) 594-4618. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

K040710

Indications For Use Statement

510(k) Number: K040710

Device Name: TEGO™ Needle Free Access Device

Indications For Use: The TEGO™ Needle Free Access Device is intended for use as an accessory to a vascular access device (catheter) used in Hemodialysis or as an accessory to an Intravascular Administration Set for the administration or withdraw of fluids to a patient through a cannula or needle placed in the vein or artery. The TEGO™ is a needle-free capping device which close the end of the catheter. The TEGO™ will permit access to the catheter without the use of needles and therefore passively aid in the reduction of needlestick injuries.

Prescription Use X	OR	Over-The-Counter-Use
(Per 21 CFR 801.109)		(optional format 1-2-9)

(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: K040710