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Cedic

510(K) K042129:
Intravenous Gravity Set with male luer slip (Cedic code F 00010)
Intravenous Gravity Set with male luer lock (Cedic code F 00027)

Safety and Effectiveness Summary

27 January, 2005

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Trade Name – Cedic srl. Intravenous Gravity Set
Common Name – Intravenous Gravity set
Classification Name – Intravascular Administration Set

The Cedic srl Intravenous Gravity Set is a universal non-DEHP tubing set that allows IV solutions to be infused into the patient in conjunction with an indwelling catheter. The drip chamber filter precludes passage of gross particle potentially generated during spiking of the IV solution container. The vent filter is 3μ aerosol microbial barrier . The device consists of a spike, drip chamber with disk filter (15 μm approx.), roller clamp, latex free flash bulb injection site, and male luer slip connector (Cedic product code: F 00010) or male luer lock connector (Cedic product code: F 00027). The components and the processes used to manufacture these Intravenous Gravity sets are substantially equivalent to like products currently legally marketed by Venusa Ltd, under K843692. The Cedic srl Intravenous Gravity set will be packaged in PE bags and sterilized per ISO 11135 guidelines.

The Cedic srl Intravenous Gravity Set is similar to the above named predicate devices in following ways:

1. It has the same intended use.
2. It uses the same components.
3. The device configuration is the same.
4. The composition of the raw materials is similar if not identical.
5. The processes used to manufacture the devices are similar if not identical.

Cedic srl Intravenous Gravity set performance tests include Solvent Bond Pull test (STM 001), Leak/Occlusion test (STM 012), Roller/Clamp functionality (STM 002), Leak test (for S 00010) (STM 011), Filter Integrity (STM 006), Retainer Adhesive Inspection (STM 003), ISO luer test (594/1/2), Check Valve performance. All testing of the Intravenous Gravity Set indicates that the device meets or exceeds the functional requirements for the device's intended use.

Based on the fact that Cedic srl Intravenous Gravity Set utilizes similar and equivalent designs, components, manufacturing processes as currently marketed products, the Cedic srl Intravenous Gravity Set is safe and effective when used as intended.

Sincerely,

Giancarlo Gagliardoni

Cedic srl, Via Liberazione 63/9, 20068 Peschiera Borromeo (MI), Italia
Tel: 0039-02-55300174 fax: 0039-02-55301487

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2005

Mr. Giancarlo Gagliardoni
General Manager
Cedic S.R.L.
Via Liberazione 63/9
Peschiera Borromeo, 20068
ITALY

Re: K042129
Trade/Device Name: Intravenous Gravity Set with Male Luer Slip (Cedic Code F00010) and Intravenous Gravity Set with Male Luer Lock (Cedic Code F00027)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: December 28, 2004
Received: December 30, 2004

Dear Mr. Gagliardoni:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use

510(k) Number: K042129

Device Name: Intravenous Gravity Set with Male Luer Slip (Cedic code F00010) and Intravenous Gravity Set with Male Luer lock (Cedic code F00027)

Indications For Use:
The Cedic srl Intravenous Gravity Set is used for IV fluid administration. This device serves as a connection between the IV fluid container and an indwelling catheter.

Prescription Use ___X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (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 K042129