K052219

SINCERT

SEP 13 2005

CANE
MEDICAL TECHNOLOGY
Canè S.r.l. società unipersonale
P.IVA - Reg. Impr. TO: 04384410017
R.E.A. TO N. 629783
Cap. Soc. Euro 10.400 i.v.

CERMET
SISTEMA DI GESTIONE CERTIFICATO
REG. N. 3506
UNI EN ISO 9001:2000
ISO 13485:2002

EXHIBIT 2

CANÈ S.r.l.
Via Pavia, 105/I 10090
Rivoli-Cascine Vica (Torino) Italy
Tel.: ++39-011-957.48.72
Fax ++39-011-959.88.80
Contact: Mario Cané, President
July 4, 2005

510(k) Summary

1. Identification of the Device:
Proprietary - Trade Name: Crono go.
Classification Name: 80 FRN.
Common/Usual Name: Ambulatory Infusion Pump.

2. Equivalent legally marketed devices
This product is similar in function and design to the Crono cleared under 510(k) number K041414.

3. Indications for Use (intended use)
The portable Crono go infusion devices have been designed for use in subcutaneous infusion of prescribed liquid medicines.

4. Description of the Device
Canè s.r.l., a company that specializes in the production of ambulatory pumps, has now produced a new generation of compact pumps: Crono, a perfect combination of high technology and innovative design.

Crono go is an ambulatory syringe infusion pump intended for the controlled administration of liquids into the patients. This means that the pump can be worn during the infusion.

Crono go combines high technology with innovative design. Thanks to the small size of the pump the patients can administer the drug any time during the day without interrupting daily life or leisure activities.

Crono go pump uses dedicated syringes which are available in two sizes: 10 and 20 ml.

Crono go has a particular mechanism which pushes directly on the rubber syringe piston, which makes it possible to reach a significant thrust force and high accuracy of administration.

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Additional bolus doses can be easily administered by pressing a dedicated button, and the administered bolus dose is shown on the display screen.

In case of occlusion, an innovative infusion control system makes it possible to proceed with the infusion automatically and, after the occlusion is eliminated, to complete it.

Crono go is fitted with a liquid cristal display which shows the time it takes to complete the delivery, the syringe size and the battery charge status.

5. Safety and Effectiveness, comparison to predicate device.
The results of bench, EMC, and user testing indicates that the new device is as safe and effective as the predicate device.

6. Substantial Equivalence Chart

Characteristic	**Crono go - K013840**	**Crono go**
Intended Use	Subcutaneous infusion of prescribed liquid medicines.	SAME
Physical characteristics	**Crono go - K013840**	**Crono go**
Size	3" x 1.85" x 1.14" (77 x 48 x 29 mm).	SAME
Weight	4.0 oz (115 g) (battery included).	SAME
Battery	Power Source Lithium battery (3V) of the 123 A type.	SAME
Infusion per impulse	22 µl.	SAME
Flow rate accuracy	+/-2%.	SAME
Max. Occlusion pressure	4.5 bar +/-1 bar.	SAME
Capacity	10 or 20 ml.	SAME

7. Conclusion
After analyzing both bench and user testing data, it is the conclusion of CANÈ S.r.l. that Crono pumps are as safe and effective as the predicate device, has few software differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2005

Mr. Carlo Musso
Quality Manager
Cane S.R.L.
Via Pavia, 105/I 10090
Rivoli-Cascine Vica (Torino)
ITALY

Re: K052219
Trade/Device Name: Crono Go
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: July 15, 2005
Received: August 15, 2005

Dear Mr. Musso:

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

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j) Indications for Use

510(k) Number (if known): K052219

Device Name: Crono go.

Indications For Use: the Crono go has been designed for use in subcutaneous infusion of prescribed liquid medicines.

Prescription Use **X** . AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C Chapman for ACW

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

510(k) Number: K052219