K052218

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CANÈ
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.

SINCERT
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
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Contact: Mario Cané, President
July 4, 2005

510(k) Summary

1. Identification of the Device:
Proprietary - Trade Name: Crono Five and Crono PCA 50.
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 Five and Crono PCA 50 infusion devices have been designed for use in subcutaneous infusion of prescribed liquid medicines.

4. Description of the Device

Crono Five is a new, innovative ambulatory infusion pump that is very appreciated by health care professionals and patients due to its small size and technical features.

Crono Five is especially suited for controlled drug administration on patients in hospital or undergoing a therapy at home. The pump is suitable for subcutaneous, intra-venous, epidural and intrathecal infusions allowing 4 different administration modalities:

1. Continuous
2. Bolus dose upon request (PCA)
3. Clinician bolus (managed by clinician)
4. Combined (continuous + bolus upon request + clinician bolus)

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

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The pump is provided with key-pad lock-out functions in order to avoid un-authorized reprogramming of the drug administration protocol.

The liquid crystal display (LCD) can show relevant information to caregivers and patients like programmed values, amount of drug delivered, remaining delivery time etc.

Crono PCA 50 is essentially the same as the Crono Five, but has a 50 ml infusion capacity.

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 PCA - K013822	Crono Five Crono PCA 50
Intended Use	subcutaneous, intra-venous, epidural and intrathecal infusions of prescribed liquid medicines.	SAME
Physical characteristics	Crono go - K013840	Crono Five Crono PCA 50
Size	3" x 1.85" x 1.14" (77 x 48 x 29 mm).	SAME For Crono PCA 50: 84.5 x 55 x 42 mm.
Weight	4.0 oz (115 g) (battery included).	SAME For Crono PCA 50: 140 g (battery included).
Battery	Power Source Lithium battery (3V) of the 123 A type.	SAME
Infusion per impulse	22 µl.	Crono Five: 5 µl. Crono PCA 50: 20 µl.
Flow rate accuracy	+/-2%.	Crono Five: +/-2%. Crono PCA 50: +/-3%.
Max. Occlusion pressure	4.5 bar +/-1 bar.	Crono Five: 2.2 bar +/-0.5 bar. Crono PCA 50: 2.2 bar +/-0.5 bar.
Capacity	10 or 20 ml.	10, 20 ml or 50 ml.

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

NOV 23 2005

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

Re: K052218
Trade/Device Name: CRONO FIVE AND CRONO PCA 50
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: II
Product Code: FRN and MEA
Dated: September 21, 2005
Received: September 26, 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): K052218

Device Name: Crono Five and Crono PCA 50.

Indications For Use: the Crono Five and Crono PCA 50 has been designed for use in subcutaneous, intravenous, epidural and intrathecal infusions 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)

FOR AOW

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

510(k) Number: K052218