K041414

EXHIBIT 2

JUL 0 8 2004

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
May 24, 2004

510(k) Summary

1. **Identification of the Device:**
   Proprietary-Trade Name: *Crono and Crono 30*
   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 K013234

3. **Indications for Use (intended use)** The portable Crono 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. The infusion pumps which use normal commercial syringes are inevitably cumbersome and thus difficult to use in everyday life. This provokes in the patients a refuse of the therapy. A special syringe, an integral part of the Crono allows an efficient reduction of the pump size. In this way, the patients can freely carry out the therapy at any time of the day, even during their everyday life. Patients who have been following a liquid medicine therapy for a long time, often experience difficulties in absorbing the drug subcutaneously; this may lead to a catheter occlusion with consequent interruption of the infusion. Crono has a particular mechanism which pushes directly the rubber syringe piston: so it is possible to reach a thrust force up to 3 times higher with respect to conventional pumps. In case of catheter occlusion, an innovative infusion control system makes it possible to proceed with the infusion automatically and, after the occlusion is eliminated, to complete it. For a better absorption of the drug, Crono makes the infusion up to 3 times more fractionated with respect to traditional pumps (22 µl per impulse, using a 10/20 ml syringe). Crono is fitted with a liquid crystal display which shows the time it takes to complete the delivery and battery charge status. The Crono 30 is essentially the same as the Crono, but has a 30 ml infusion capacity. It infuses at a rate of 33 µl per impulse.

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, K013234**	***Crono and Crono 30***
Intended Use:	subcutaneous infusion of prescribed liquid medicines.	SAME
Physical characteristics:		
Power Source	Lithium battery (3V) of the 123 A type	SAME
Infusion per impulse	22 µl	22µl or 33 µl for Crono 30 with 30 ml syringe
Size	3" x 1.85" x 1.14" (77 x 48 x 29 mm)	SAME For Crono 30: 3.15" x 1.89" x 1.38" (80 x 48 x 35 mm)
Weight	4.0 oz (115 g) (battery included).	SAME Crono 30: 125 g. (battery included)
Capacity	10 or 20 ml	10, 20, or 30 ml
Warranty:	2 years	SAME

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of CANÈ S.r.l. that the Crono and Crono 30 pumps are as safe and effective as the predicate device, has few technological 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

JUL 0 8 2004

Cane S.r.l.
C/O Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K041414
Trade/Device Name: Crono and Crono 30
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: June 28, 2004
Received: July 1, 2004

Dear Mr. Kamm:

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.

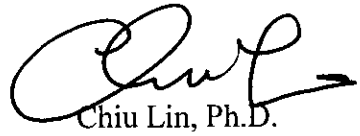
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

Indications for Use

510(k) Number (if known):_____

Device Name: Crono and Crono 30

Indications For Use: The Crono and Crono 30 ambulatory infusion pump devices have 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)

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

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