K013776

APR 2 6 2002

EXHIBIT 2

CANÈ S.r.l.
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Contact: Mario Cané, President
January 30, 2002

510(k) Summary of Safety and Effectiveness

1. **Identification of the Device:**
   Proprietary-Trade Name: Microjet *CD4, CD4/20*
   Classification Name: 80 FRN
   Common/Usual Name: Ambulatory Infusion Pump

2. **Equivalent legally marketed devices** This product is similar in function to the Cadd-Legacy 1 Ambulatory Infusion Pump , Sims Deltec, Inc., K982838

3. **Indications for Use (intended use)** The portable CD4, CD4/20 infusion devices have been designed only for use in subcutaneous infusion of prescribed liquid medicines.

4. **Description of the Device**: This infusion device has been manufactured since 1978 and has, during all this time, proved to be highly reliable in terms of sturdiness, reliability, accuracy and easy operation. Moreover, it does not require particular maintenance work. Microjet CD4 is a portable, battery-operated infusion device for use with 5 ml and 10 ml syringes (20 ml syringes are used with model CD4/20). A special micromotor actuates mechanical members that transform the motor rotary motion into the pusher linear motion which, in turn, causes the syringe piston to advance. The infusion device operating features enable to make infusions with varying amounts of medicine and different infusion times. During infusion, the motor is controlled by a special electronic circuit with regular pulses; therefore, infusion is carried out by delivering small amounts of medicine repeated with the passing of time.

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	**Cadd-Legacy 1 Ambulatory Infusion Pump , Sims Deltec, Inc., K982838**	**Microjet *CD4, CD4/20***
Intended Use:	Intravenous Intra-arterial Subcutaneous Intraperitoneal Epidural Intrathecal	Subcutaneous only
Physical characteristics:		
Power Source	2 AA alkaline batteries, AC Adapter	9 volt Alkaline battery
Size	4.4 x 3.8 x 1.6 x in (112x 95x41 mm)	170 x 70 x 20 mm
Weight	13.8 oz (392 grams)	Approximately 220 g (including alkaline battery)
Capacity	10 ml	Disposable 5 ml or 10 ml syringes (the CD4/20 model has metal jaws to accommodate 20 ml syringes)
Warranty:	1 year	SAME

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of CANÈ S.r.l. that the Microjet CD/4, CD4/20 is 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

Cane S. R. I
C/O Mr. Daniel Kamm
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

APR 26 2002

Re: K013776
Trade/Device Name: Microjet CD4/20 Ambulatory Infusion Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: April 23, 2002
Received: May 8, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Susan Runner

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number K013776

Device Name: Microjet CD4, CD4/20 ambulatory infusion pump

Indications for Use: The **Microjet CD4, CD4/20 ambulatory infusion pump** device has been designed for use in subcutaneous infusion of prescribed liquid medicines.

_____ _____ _____ _____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013776