K051252

MAY 27 2005

SUMMARY

In accordance with 21 CFR 807.92 Micrel Medical submits the following information:

Submitter:	Micrel Medical Devices, S.A. 4 Ithakis Street Pallini 15351 GREECE
Telephone:	+30210 6032333
Facsimile:	+3-210 6032335
Contact:	Alexandre Tsoukalis, Technical Director
Date:	March 12, 2005
Device Name:	Micropump MP-101
Common Name:	Syringe Pump
Classification Name:	Infusion Pump (80 FRN)
Regulation Number:	21 CFR 880.5725
Predicate Device:	A. Cane S.r.l. Crono H B. Smiths Graseby MS-16 (K830423)

Description of the Device: Ambulatory Infusion Pump, battery operated, for use with any syringe type from 10 ml to 20 ml, set at a particular speed. The LCD and units are displayed on the front panel. The Pump has an up-down-enter keyboard user interface.

Intended Use: The MP 101 Micropump is a battery-operated portable infusion pump designed for use in subcutaneous and intravenous infusion of prescribed liquid medicines.

MP 101 is not indicated to infuse blood.

The Predicate devices have the same intended use as the Proposed device.

Technological Characteristic Comparison with Predicate Device: The technological features of the Proposed device do not differ significantly from the Predicate devices. The Proposed device MP 101 and the Predicate devices are syringe drivers, are battery operated, have the same intended use; and flow rate reading, accuracy and materials are identical to the Predicate devices. The devices are equal in size and both have a 01 to 99 mm/Hr Infusion Rate range. An enhanced safety feature of the Proposed device uses a magnetic drum and two hall-effect sensors. The devices meet the IEC60601-1 standard covering the single fault condition and IEC60601-2-24, except for clause 54.101 which is addressed by both manufacturer with similar counter measures as described in the

comparison table and in the risk analysis for this product in accordance with ISO 14971. The Proposed device and Predicate A use an LCD and keyboard, Predicate B uses rotary switches for each digit.

Performance Data: The performance data indicate that the device will meet specified requirements and is substantially equivalent to the predicate devices. Product Safety testing demonstrates single fault condition for software/hardware interaction. Software safety tests demonstrate that alarms meet safety specifications. A risk assessment was performed utilizing Fault Tree Analysis and ISO 14971.

end

Third Party Review Quality Assessment

Section 1 – Submission Information

510(k) No.: K051252 Third Party Organization: TUV America

Third Party's Primary Reviewer(s): Stefan Reiss

ODE/OIVD Division: DAGID Branch/Team: GHDB

Section 2 – 510(k) Decision

Third party recommendation: SE ✓ NSE ____ Other (specify): _____

ODE/OIVD final decision: SE ✓ NSE ____ Other (specify): _____

Section 3 – Assessment of Third Party Review

Review Element	Rating (check one)		
	Adequate	Minor Issue(s)	Major Issue(s)
a. Determination of device eligibility for third party review	✓		
b. Extent of pre-submission consultation with ODE/OIVD division	✓		
c. Organization and format of review documentation	✓		
d. Determination of 510(k) administrative completeness (screening review)	✓		
e. Summary of device characteristics, intended use, and performance (including accessories, if applicable) and reason for 510(k) submission	✓		
f. Comparison to legally marketed devices—identification and analysis of key similarities and differences	✓		
g. Rationale for conclusions and recommendation	✓		
h. Use of guidance documents and standards	✓		
i. Resolution of 510(k) deficiencies and FDA requests for additional information	✓		
j. Scope of reviewer expertise and use of consulting reviewers	✓		
k. Other (specify):	✓		

Comments (explanation of ratings/issues): _____

Section 4 – ODE/OIVD Assessor Information

Assessed by: [signature] Date: 5/27 Tel. No.: 301-827-5283

Routing: Division--Clip completed assessment (this page only) to inside front cover of 510(k).
DMC--Forward this page only to Eric Rechen, POS/ODE, Rm. 120J, Corp. Blvd. (HFZ-402).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2005

Micrel Medical Devices S.A.
C/O Mr. Stefan Preiss
Responsible Third Party Official
TUV America, Incorporated
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K051252
Trade/Device Name: Micropump MP 101
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: May 13, 2005
Received: May 16, 2005

Dear Mr. Preiss:

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

Statement of Indications for Use

510(k) Number : K051252
Device Name: Micropump MP 101

Indications For Use:

The MP 101 Micropump is a battery-operated portable infusion pump designed for use in subcutaneous and intravenous infusion of prescribed liquid medicines.

MP 101 is not indicated to infuse blood.

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

510(k) Number K051252