MAY 8 2007

K070529

510(k) Summary

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter's Corporate Address:**	Definitive Medical Technologies 4 Hamelacha St. North Industrial Zone Lod, Israel 71520 www.definitive.com
1. (b)	***Manufacturer Address:***	Definitive Medical Technologies, Ltd. 4 Hamelacha Street North Industrial Zone Lod, Israel 71520
	Mfg. Phone:	972-8-925-1171
	Contact Person:	Boaz Bartov CEO
	Date:	12.12.06
2.	***Device & Classification Name:***	Infusion Pump (Class 2), Product Code FRN, 21 CFR 880.5725- Trade-name of device: AFF (MARK I) Volumetric Infusion Pump
3.	***Predicate Devices:***	B. Braun Infusomatic Infusion Pump (K003029) Sigma International 8000 Infusion Pump (K950766) Baxter Flo-Gard Infusion Pump (K915522)
4.	***Description:***	The Definitive Medical Technologies AFF (Mark I) Volumetric Infusion Pump is a medical device used to pump fluids into a patient in a controlled manner. It is suitable for delivering a wide range of infusions, including medications, as well as providing TPN (Total Parenteral Nutrition) and PCA (Patient Control Analgesia) operating modes. It is also compatible with the majority of IV procedures and most standard IV sets.
5.	***Intended Use:***	The AFF (MARK I) Volumetric Infusion Pump is indicated for delivering infusions of medications, as well as providing TPN (Total Parenteral Nutrition) and PCA (Patient Control Analgesia). It is intended for use in hospitals, ambulatory & nursing home (extended care) settings, or home care environments.
6.	***Comparison of Technological Characteristics:***	With respect to technology, the AFF (MARK I) Volumetric Infusion Pump is substantially equivalent to its predicate devices. All of the devices rely upon peristaltic mechanisms to pump fluids intravenously through IV sets. The manner of control and safety features for each device is similar. Extensive testing has confirmed the performance and safety of the AFF (MARK I) Volumetric Infusion Pump.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 8 2007

Definitive Medical Technologies, Limited
C/O Mr. J.A. Van Vugt
Responsible Third Party Official
Kema Quality B.V.
4377 County Line Road
Chalfont, Pennsylvania 18914

Re: K070529
Trade/Device Name: AFF (MARK I) Volumetric Infusion Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: May 1, 2007
Received: May 2, 2007

Dear Mr. Vugt:

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.

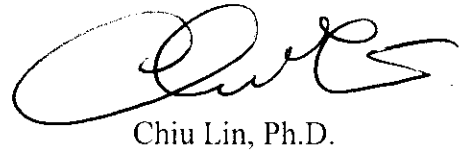
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

K979529

510(k) Number (if known):

Device Name: AFF (MARK I) Volumetric Infusion Pump

Indications For Use: The AFF (MARK I) Volumetric Infusion Pump is indicated for delivering infusions of medications, as well as providing TPN (Total Parenteral Nutrition) and PCA (Patient Control Analgesia). It is intended for use in hospitals, ambulatory & nursing home (extended care) settings, and home care environments.

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)