K981816

Curlin Healthcare Products, Inc.

DEC 4 1998

**510(k) Summary**

Submitter: Becton Dickinson Curlin, LLC

Address: 15751 Graham St.
Huntington Beach, CA 92649

Phone number: (714) 897-9301

Fax number: (714) 895-4364

Contact person: Procedural Matters - Charles J. Welle, (801) 565-2568
Technical Matters - Maher Moubayed, (714) 893-2438 extension: 225

Date Prepared: April 30, 1998

Trade Name: CareMED5™ Ambulatory Volumetric Infusion Pump

Common name: Electromechanical Curvilinear (Peristaltic Action) Volumetric Infusion Pump

Classification name: Infusion Pump

Substantial equivalence claimed to:

1. Sabratek 6060 HOMERUN™ VOLUMETRIC INFUSION PUMP, 510(k) Number: K941984.
2. Abbott Ambulatory Infusion Manager Plus (Abbott AIM® Plus), 510(k) Number: Unknown.

Basic Description:
The "CareMED5" Ambulatory Infusion Pump is a small, lightweight electro-mechanical pump utilizing a microcomputer and a Curvilinear (peristaltic type action) volumetric pumping mechanism that produces accurate fluid flow in the PVC tubing with very low wear effect on the tubing. The pump has 5 IV therapy modes and can be programmed for Continuous, TPN Automatic Ramping, Intermittent Delivery, Variable Program Delivery and Patient-Controlled Analgesia.

Statement of Intended Use:
The CareMED5 Multi-Therapy (5) Ambulatory Infusion Pump System with Disposable PVC Administration Tubing Sets and User Accessories, provides a means for the volumetric delivery of fluids used in Parenteral, Enteral, Epidural, Subcutaneous and Intravenous Applications.



15751 Graham Street, Huntington Beach, CA. 92649 Phone: (714) 893-2438 Fax: (714) 894-2602

Curlin

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Summary of Technology Characteristics:

The CareMED5 pump has a Curvilinear volumetric pumping mechanism that moves fluid through the PVC IV Set tubing by the action of 7 fingers sequentially pressing on the IV set tubing. The design of the mechanism produces an action that does not crush the IV tubing except for very localized pinch off area under the fingers, which results in very low wear on the tubing. The mechanism is driven through a worm gear by a DC motor with high efficiency. Ease of operating the pump is provided by a graphic LCD display which can present a large amount of operating information to the user and a numeric keypad with menu scroll keys, so that by following the "therapy specific" display prompts, operation of the pump is largely self evident. The pump is powered by either low cost "C" cell batteries, or external power sources. The pump has self-diagnostics to check critical systems during start-up and for monitoring of performance while operating, as well as alarm sensors for detecting air, input and output occlusions in the IV set tubing, and the closure of the mechanism door. A history log records operating and alarm events and a communications data port provides remote operation and access to the history log for the downloading of recorded events. The pump has a rugged outer case and is water resistant with an easily operated door and keyed interfaces between the Administration IV Sets and the pump mechanism. Sterile administration sets made with all Class VI materials in the fluid path, are available with macrobore and microbore tubing and various sized filters and "Y" injection sites. All administration sets have automatic tubing clamps that work with the pump mechanism for anti-free flow protection when the IV Set is removed from the pump.

The pump has accessories for user convenience that include:

- External Rechargeable Battery Pack
- External Battery Eliminator/Battery Charger
- Lockable Plastic Reservoir Case (to hold pump and fluid container) with removable Pole Clamp
- Holster Case for Pump with removable Pole Clamp
- Soft Carry Cases of small, medium and large size
- External Patient Bolus Switch and Cable
- Hard Carry Case for Pump and Select Accessories



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 4 1998

Mr. Charles J. Welle
Becton Dickinson Curlin, LCC
15751 Graham Street
Huntington Beach, California 92649

Re: K981816
Trade Name: CUE™ Ambulatory Volumetric Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: September 14, 1998
Received: September 16, 1998

Dear Mr. Welle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

510(k) Number (if known): _____

Device Name: Ambulatory Volumetric Infusion Pump

Indications for Use:

The CareMED5™ infusion pump can be used for intravenous, intra-arterial, epidural, subcutaneous, or enteral infusions. Any therapy should be overseen by a physician or a certified, licensed healthcare practitioner. The infusion pump can provide therapy to patients/users who are ambulatory and needed an alternative to receiving their medication in a restricted manner (hospital or clinic). Typically, these patients are capable of being given instruction for performing basic tasks in operating the pump and maintaining medical care for themselves, or are assisted in these tasks by having a caregiver closely by, or living with them. All patients and caregivers must be instructed in the use of the CareMED5™ by a qualified clinician and demonstrate an adequate level of proficiency in the use of the pump.

The CareMED5™ is small, lightweight and is designed to have exceptional ease of use so theat after learning the pump features and basic of programming, the pump can be operated and can be customized to the specific needs of each individual patient without the need to constantly refer to the User's Manual.

(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 Dental, Infection Control,
and General Hospital Devices

510(k) Number _____

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