K031339

JUL 1 1 2003

Special 510(k) Summary

1. Company Identification

Mallinckrodt Inc., Liebel-Flarsheim Business
2111 East Galbraith Road
Cincinnati, OH 45237

Establishment Registration: 1518293

2. Contact Person

Ellis Rogers
Quality Manager
Phone: (513) 948-4041
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3. 510(k) Preparation Date

4/15/2003

4. Device Name

Trade Name: CT9000ADV / OptiBolus
Common Name: Power Injector

5. Device Classification

Class II

6. Indications for Use

The CT9000ADV is designed to inject a radiopaque contrast media into a patient's vascular system, which enhances diagnostic images obtained with computed tomography (i.e. "CT"). Each injection is accomplished with a motor-driven syringe mechanism with microprocessor control of the flow rate, volume and timing.

7. Description of Device

The CT9000ADV / OptiBolus Injection System delivers radiographic contrast media at a controlled flow rate and volume into a patient's vascular system for the purpose of obtaining enhanced diagnostic images. The OptiBolus feature is used to enable an exponential decaying flow rate injection that will optimize the contrast usage and provide an extended period of uniform enhancement. The OptiBolus feature can be turned on or off by the user for any given injection protocol.

The major components of the system are:

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1. **Power Head**- The CT 9000ADV / OptiBolus Powerhead is contained in a sturdy metal case. The Powerhead contains the operator interfaces for viewing injection information, controlling the fill and expel operation, starting and stopping an injection, indications for enabled and injecting states and the interface for connection of the various syringes. The Powerhead communicates its gathered information to the Power Pack.

2. **Power Pack**- Contains the power supply and main microprocessor. The power supply converts the line voltage to the working voltage for the powerhead and console (approximately 24-vdc). The main processor provides a centralized control system for all system functions. The Powerhead and Console each contain a remote microprocessor that is used to control their localized functions.

3. **Console**- Communicates with the Power Pack to program and initiate injection protocols, displays the injection status, and displays an injection timer. The Console provides the means for the operator to enable, disable and view an OptiBolus injection. The Console display provides a simulated display that represents the OptiBolus injection as it progresses.

4. **Syringes**- The CT9000ADV / OptiBolus Injection System accommodates the Mallinckrodt 125-ml pre-filled syringe styles. It is also accommodates the Liebel-Flarsheim 200-ml syringe. These syringes are commonplace on the market.

8. Substantial Equivalence

The Predicate injector to the CT9000ADV / OptiBolus Injection System is the CT 8000 Digital Injection System, 510(k) number K912944 currently marketed under the name CT 9000ADV.

The predicate device (CT 8000 Digital Injection System) is designed to meet both the ordinary needs of the market as well as advanced needs. **Both devices share the same fundamental technology.** The CT9000ADV / OptiBolus version of the system however is designed to provide a bolus shaping injection. A bolus shaping injection is an injection that ramps to a set flow rate and then once achieved, begins to deay using an exponential algorithm to a preset minimum flow rate. This injection process injection patented by Drs. Heiken, Bae and Brinks.

Below is a table comparing a predicate device to the proposed CT9000ADV / OptiBolus Injection System.

Feature	**CT9000ADV / OptiBolus** Injector System (New Device)	**CT 8000** Digital Injection System *Predicate Device* (K912944)
Multi-phasic Injections	4 phases per protocol or a single OptiBolus injection protocol	4 phases per protocol
Protocol Storage	12 protocols	12 protocols
X-ray Scan Delay Timer	99 seconds	99 seconds
Syringe Sizes	All pre-filled volumes of Mallinckrodt 125-ml; Liebel-Flarsheim 200-ml	All pre-filled volumes of Mallinckrodt 125-ml; Liebel-Flarsheim 200-ml
Syringe Drive System	Electromechanical	Electromechanical
Syringe Heater	Yes	Yes
Syringe Fill Rate	2 to 15-ml/sec	2 to 15-ml/sec
Flow Rate	0.1 to 8-ml/sec	0.1 to 8-ml/sec
Max Pressure Limit	300 psi	300 psi

Pressure Limit Control	User settable	User settable
Flushing System	Manual	Manual
Remote Start	Yes	Yes
Display Technology	LCD	LCD
Program Memory	Yes	Yes
Number of Control Panel Buttons	8 soft-keys on touchscreen interface – same functions as predicate device.	8
Post Injection Readout	Yes	Yes
Printer Option	Yes	Yes
Interface	Relays & Optical Couplings	Relays & Optical Couplings
Safety Stop Mechanism	Electrical Stop when injection parameters are out of spec.	Electrical Stop when injection parameters are out of spec.
User Interface		
Remote Control	Yes	Yes
Fill/ Expel Control	Push buttons on Power Head and Manual Knob	Push buttons on Power Head and Manual Knob
Programming Injections	Buttons on Console	Buttons on Console
Volume Remaining Display	Display on Powerhead and Console	Display on Powerhead and Console
Materials	Plastic and metal	Plastic and metal
Anatomical Injection Site	Injection into venous system	Injection into venous system
Function and Purpose	The injection of X-ray contrast agents for the purpose of enhancing diagnostic CT imaging of humans.	The injection of X-ray contrast agents for the purpose of enhancing diagnostic CT imaging of humans.
Target Population	Humans	Humans
Sterility (Syringe)	Injectors are not sterile products, Syringes and Disposables are provided sterile	Injectors are not sterile products, Syringes and Disposables are provided sterile

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2003

Mallinckrodt, Inc.
c/o Mr. Ellis Rogers
Liebel-Flarsheim
2111 E. Galbraith Road
Cincinnati, OH 45237

Re: K031339
CT9000ADV/OptiBolus Injection System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: June 11, 2003
Received: June 17, 2003

Dear Mr. Rogers:

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) 594-4646. 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) you may obtain. 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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2. Statement of Indications

The intended use of the CT9000ADV / OptiBolus Injection System is the same as the predicate CT 8000 Digital Injection System.

Indications for Use: The CT9000ADV is designed to inject a radiopaque contrast media into a patient's vascular system, which enhances diagnostic images obtained with computed tomography (i.e. "CT"). Each injection is accomplished with a motor-driven syringe mechanism with microprocessor control of the flow rate, volume and timing.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031339

Prescription Use Only