NOV 3 0 2004

K042744

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
Fax: (513) 948-5708
Email: Ellis.Rogers@TycoHealthcare.com

3. 510(k) Preparation Date

10/2/04

4. Device Name

Trade Name: OptiVantage DH Injection System
Common Name: Power Injector

5. Device Classification

Class II

6. Indications for Use

The OptiVantage DH Injection System is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

7. Description of Device

The OptiVantage DH Injection System delivers radiographic contrast media and/or saline at a controlled flow rate and volume into a patient's vascular system for the purpose of obtaining enhanced diagnostic images. The OptiVantage is made up of the following major components:

- **Power Head**- Contains two electromechanical syringe drive systems, the syringe holding mechanisms, the main microprocessor, control electronics, control keypad for programming and initiating injection protocols, a status display, and two purge/retract manual knobs. The OptiVantage uses a drive system that is similar to existing Mallinckrodt injectors in the marketplace. It uses a motor and gearbox coupled to a ball screw. The ball screw drives a ram that attaches to the syringe plunger in order to fill or expel the contents of the syringe.

- **Power Supply**- The power supply converts the line voltage to the working voltage for the power head and console (approximately 24-vdc).

- **Console** - Communicates with the Power Head to program and initiate injection protocols, displays the injection status, and displays a timer.

- **Syringes** - The OptiVantage Injection System accommodates the Mallinckrodt 125-ml pre-filled syringe styles and pre-filled saline syringes as well as a 200 ml front loading empty syringe. These syringes are commonplace on the market.

8. Substantial Equivalence

The predicate injector to the OptiVantage DH Injection System is the CT9000ADV / OptiBolus Injection System, 510(k) number K031339.

The OptiVantage DH Injector System maintains the same intended use as the predicate device. It is intended to be used for the specific purpose of injecting radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

The OptiVantage DH Injector System consists of four main components in the same manner as the predicate device: a Power Head, a Console, a Power Supply, and Syringes. Both the OptiVantage DH Injector System and the predicate device consist of the same fundamental technology. They are motor driven, electromechanical devices which are software controlled.

The OptiVantage DH Injector System differs primarily from the predicate device in that it contains a second identical drive system as a feature to conveniently inject a flushing solution (i.e. saline) in conjunction with the main contrast injection. The flushing injection can currently be accomplished with the predicate device by interfacing to another injector (K022116). The OptiVantage DH Injector System simply offers a more convenient method for accomplishing this.

Below is a table that compares the predicate device to the proposed OptiVantage Injection System.

Feature	OptiVantage Injector System (New Device)	CT9000ADV / OptiBolus Injection System *Predicate Device* (K031339)
Intended Use	Intended to be used for the specific purpose of injecting radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment	Intended to be used for the specific purpose of injecting radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment
Multi-phasic Injections	6 phases per protocol	4 phases per protocol
OptiBolus	Yes	Yes
Protocol Storage	40 protocols	12 protocols
Syringe Sizes	All pre-filled volumes of Mallinckrodt 125-ml contrast syringes & Liebel-Flarsheim 200 ml empty syringe	All pre-filled volumes of Mallinckrodt 125-ml contrast syringes & Liebel-Flarsheim 200 ml empty syringe
Single or Dual Syringe Modality	Single syringe and Dual syringe capability	Single syringe and Dual syringe (when interfaced)
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 10 ml/sec	0.1 to 9.9 ml/sec
Max Pressure Limit	325 psi	325 psi
Pressure Limit	User-settable or automatic	User-settable

Feature	**OptiVantage** Injector System (New Device)	**CT9000ADV / OptiBolus** Injection System *Predicate Device* (K031339)
Control	25 psi increments	25 psi increments
Flushing System	Manual or via injector	Manual or via injector (with interface)
Remote Start	Yes	Yes
Scan Delay	0 – 600 seconds	0 – 500 seconds
Phase Delays	0 – 600 seconds plus Pause	0 – 254 seconds plus Pause
Console Controls	Touch screen Color LCD	Touch screen Color LCD
Power head Controls	Touch screen Color LCD	Keypad
Post Injection Readout	Yes	Yes
OEM Interface (Optional)	Relays & Optical Couplings or Serial	Relays & Optical Couplings
Safety Stop Mechanism	Electrical Stop when injection parameters are out of specifications	Electrical Stop when injection parameters are out of specifications
Remote Check for Air	Yes	Yes
Volume Remaining Display	Displayed on Power Head and Console	Displayed on Power Head and Console
Used Syringe Detection	Yes	Yes
Materials	Plastic and metal	Plastic and metal
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

NOV 3 0 2004

Mallinckrodt, Inc.
c/o Mr. Ellis Rogers
Quality Manager
2111E East Galbraith Road
Cincinnati, OH 45237

Re: K042744
OptiVantage DH Power Injection System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: November 1, 2004
Received: November 2, 2004

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 (240) 276-0120. 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/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

Attachment 5

Indications for Use

510(k) Number (if known): K042744

Device Name: OptiVantage DH Power Injection System

Indications For Use:

The OptiVantage DH Injection System is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Volmer

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K042744