K022116

JUL 2 6 2002

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
Manager, Plant QA
Phone: (513) 948-4041
Fax: (513) 948-5708

3. 510(k) Preparation Date

6/27/2002

4. Device Name

Trade Name: ELPH
Common Name: Power Injector

5. Device Classification

Class II

6. Indications for Use

The ELPH Injection System used to inject Contrast Media and a flushing solution in order to enhance X-ray images.

7. Description of Device

The ELPH Injection System will deliver 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 ELPH is made up of the following major components:

Power Head- Contains the electromechanical syringe drive system, the syringe holding mechanism, the main microprocessor, control electronics, control keypad for programming and initiating injection protocols, a status display, and a purge/retract trigger.

Power Pack- Contains the power supply and interface. The interface is made up of relays and optical couplings that provide communication between devices. One use for the interface is to harmonize two injectors so as to provide greater contrast volume capability or a flushing solution.

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

Syringes- Accommodates the Mallinckrodt 125-ml pre-filled syringe styles. It is also accommodates the Liebel-Flarsheim 130-ml syringe (Part Number 600172). These syringes are commonplace on the market.

8. Substantial Equivalence

The Predicate device to the ELPH Injection System is the CT 8000 Digital Injection System (K912944), currently marketed under the name CT 9000ADV. The predicate device is designed to meet both the ordinary needs of the market as well as advanced needs. The ELPH on the other hand is designed to meet only the ordinary needs and is therefore less expensive, smaller and less complicated to operate. Features such as stored protocols, multi-phasic injections, high flow rate, and optional printer have been omitted in order to reduce cost and simplify the user interface.

With an optional interface, the ELPH Injection System may be joined with another ELPH Injector or other compatible injector. Interfacing two injectors and connecting the syringes through "Y" tubing enables greater deliverable X-ray contrast volumes. Interfacing two ELPH Injection Systems provides a maximum of 260-ml capability, while the predicate injector is limited to 200-ml. The Angiomat CT contrast injector (K860204) has been marketed by Liebel-Flarsheim and is capable of delivering up to 260-ml of contrast. The package insert for the X-ray contrast media defines the maximum allowable dose based on patient parameters.

Another application for interfacing two injectors is to provide a means to automatically flush the injection site before and/or after a contrast injection. This would be accomplished by filling one of the syringes with a flushing agent, normally saline. With the predicate device, the flush is done manually with a separate hand-held flushing syringe. Automatic flushing capability is available on other marketed injectors such as the Optistar MR Injection System, 510(k) number K984088.

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

Feature	**ELPH** Injector System (New Device)	**CT 8000** Digital Injection System *Predicate Device* (K912944)
Multi-phasic Injections	Single phase	4 phases per protocol
Protocol Storage	1 protocol	12 protocols
X-ray Scan Delay Timer	Manual, 20 minutes	99 seconds
Syringe Sizes	All pre-filled volumes of Mallinckrodt 125-ml; 130-ml (L-F # 600172)	All pre-filled volumes of Mallinckrodt 125-ml; Liebel-Flarsheim 200-ml
Syringe Drive System	Electromechanical	Electromechanical
Syringe Heater	No	Yes
Syringe Fill Rate	1 to 8-ml/sec	2 to 15-ml/sec
Flow Rate	0.1 to 6-ml/sec	0.1 to 8-ml/sec
Max Pressure Limit	250 psi	300 psi
Pressure Limit Control	Automatic based on flow rate	User settable
Flushing System	Manual; Automatic with interface option	Manual
Remote Start	Yes	Yes
Display Technology	LED	LCD
Program Memory	Yes	Yes
Number of Control Panel Buttons	5	8
Post Injection Readout	Yes	Yes
Printer Option	No	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	Purge/Retract trigger	Push buttons on Power Head and Manual Knob
Programming Injections	Buttons on Console and Powerhead	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 and flushing solutions for the purpose of enhancing diagnostic 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

Mallinckrodt Inc., Liebel-Flarsheim Business
Mr. Ellis Rogers
Manager, Plant QA
2111 East Galbraith Road
Cincinnati, OH 45237

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Re: K022116
ELPH Injection System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: Class II (two)
Product Code: 74 DXT
Dated: June 28, 2002
Received: July 1, 2002

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.

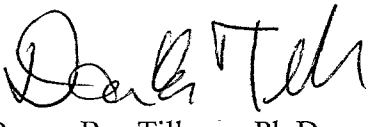
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. 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). 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,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022116

2. Statement of Indications

The intended use of the ELPH Injection System is the same as the predicate CT 8000 Digital Injection System.

Indications for Use: The ELPH Injection System is a contrast delivery system which 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.

Division of Cardiovascular & Respiratory Devices
510(k) Number K022116

Prescription Use X
(Per 21 CFR 801.109)