K073592

MAY - 7 2008

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510(k) Summary

1. Company Identification

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

Establishment Registration: 1518293

2. Contact Person

Dale Moore
Quality Manager
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3. 510(k) Preparation Date

12/19/07

4. Device Name

Trade Name:	Optistar Elite Injection System
Common Name:	Power Injector
Classification Name	Injector and Syringe, Angiographic (21 CFR 870.1650, product code DXT)

5. Device Classification

Class II

6. Indications for Use

The Optistar Elite Injection System is a contrast delivery system and is designed to inject MR contrast media and flushing solutions into a patient's vascular system to obtain diagnostic images when used with Magnetic Resonance Imaging equipment.

7. Description of Device

The Optistar Elite is a delivery system designed to inject image enhancing MR contrast media and flushing solutions into the vascular system for the purpose of obtaining enhanced diagnostic images. The Optistar Elite consists of 4 main components and syringes, just like the predicate device:

Power Head- Contains two piezoelectric motors that drive two lead screw rams, the syringe holding mechanisms, the main microprocessor, two sets of forward and reverse keys, one set of accelerator keys, check air key, start key, stop key, syringe size sensors and indicators, injection indication lamps, and pivot adjustment knob. The Optistar Elite uses a drive system that is similar to the existing Mallinckrodt MR injector in the marketplace. The piezoelectric motors drive the rams that are designed to push against the syringe pushrods (or plunger in 125 ml syringes) to expel the fluid from the barrel of the syringe.

Console – The console is the main user interface for the injector system. It allows the user to input injection parameters via a touch screen as well as view the results of an injection. The console incorporates a remote hand switch for starting or stopping an injection. It communicates with the Power Head to program and initiate injection protocols, displays the injection status, and displays a timer. The console contains the system on/off control.

Power Control - The power control is the interface between the console and the power head. The power control processes the information input by the user at the console and relays this information to the power head. The power control also supplies DC voltage to the power head. The power control receives its power from the power supply. The power control is the servo drive for the motors in the power head.

Power Supply – The power supply converts AC line voltage to DC voltage to power the Console and Power Control. It also passes communications from the console to power control.

Syringes - The Optistar Elite Injection System accommodates the Mallinckrodt Optimark pre-filled syringes (10 ml, 15 ml, 20 ml, 30 ml), the Mallinckrodt pre-filled saline syringes (50ml and 125 ml) and the empty disposable 60 ml Mallinckrodt syringes.

8. Substantial Equivalence

The predicate injector to the Optistar Elite Injection System is the Optistar MR Injection System, 510(k) number K984088

The Optistar Elite Injector System maintains the same intended use as the predicate device. The Optistar Elite is intended for injecting MR contrast agents and flushing solutions for the purpose of enhancing diagnostic imaging of humans. The stated Indications for Use differ from those of the predicate device, in that the predicate device included the magnetic field strength limitation of 1.5 Tesla in the Indications statement itself. The proposed device has been validated for use in a magnetic field strength up to 3.0 Tesla by testing it with a variety of scanners with field strengths up to 3.0 Tesla. This limitation has been removed from the Indications statement, and will be addressed in the Warnings and Precautions.

The Optistar Elite Injector System consists of four main components and syringes in the same manner as the predicate device: a Power Head, a Console, a Power Supply, Power Control and Syringes. Both the Optistar Elite Injector System and the predicate device consist of the same fundamental technology. They are piezoelectric mechanical devices which are software controlled.

The Optistar Elite Injector System is similar to 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 MR contrast injection.

The primary difference between the Optistar Elite and the predicate device is the addition of several features that make the Elite more user friendly. The addition of a patency check function and timing bolus are the main examples of functionality that was present in the predicate device, but is much more convenient in the Elite. The graphical user interface on the Elite is easier to program and has a more modern look.

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

Feature	Optistar Elite Injection System	Optistar MR Injection System Injection System *Predicate Device* (K984088)
Intended Use	Intended for injecting MR contrast agents and flushing solutions for the purpose of enhancing diagnostic imaging of humans.	Intended for injecting MR contrast agents and flushing solutions for the purpose of enhancing diagnostic imaging of humans.
MR Environment	Up to 3 Tesla.	Up to 1.5 Tesla.
Multi-phasic Injections	Yes – multiple phases per protocol	Yes – multiple phases per protocol
Protocol Storage	40 protocols	40 protocols
Injection History	Stores last 48 injection results	Stores last 12 injection results
Syringe Sizes	Prefilled Contrast 10ml, 15ml, 20ml, 30ml syringes Prefilled Saline 50ml & 125 ml syringes 60 ml disposable syringes	Prefilled Contrast 10ml, 15ml, 20ml, 30ml syringes 25ml & 60 ml disposable syringes
Single or Dual Syringe Modality	Single syringe and Dual syringe capability	Single syringe and Dual syringe capability
Syringe Drive System	Piezoelectric	Piezoelectric
Syringe Heater	No	No
Flow Rate	A side: MR contrast media 10, 15, 20, 30ml syringes: 0.1-8.0 ml/sec 60 ml syringes: 0.1-10 ml/sec B side: Saline 60 ml syringes: 0.1-8.0 ml/sec 50 & 125 ml syringes: 0.1-8.0 ml/sec	A side: MR contrast media 10, 15, 20, 25, 30ml syringes: 0.1-8.0 ml/sec 60 ml syringes: 0.1-10 ml/sec B side: Saline 60 ml syringes: 0.1-7.0 ml/sec
Max Pressure Limit	200 psi	200 psi
Pressure Limit Control	User-settable 10 psi increments	User-settable 10 psi increments
Flushing System	Manual or via injector	Manual or via injector
Ability to check patency	Yes – Manual or using Patency Check	Yes - Manual
Ability to run a Test Injection	Yes – Using Timing Bolus feature	Yes – Running 2 separate injections
Remote Start	Yes	Yes
Scan Delay	0 – 60 seconds	0 – 60 Seconds
Phase Delays	Yes	No
Inject Delay	Yes	No
Console Controls	Touch screen Color LCD	Touch screen Color LCD
Power head Controls	Keypad	Buttons
Post Injection Readout	Yes	Yes
Enable Sequence	Yes	Yes
Check for Air Button	Yes	Yes
Volume Remaining Display	Displayed on Console	Displayed on Console
Mode for keeping fluid path open	Yes – Drip Mode	Yes – Drip Mode
Ram Retraction	Manual or automatic	Manual
Materials	Plastic and non-ferrous	Plastic and non-ferrous
Sterility	Injectors are not sterile products. Syringes and Disposables are provided sterile.	Injectors are not sterile products. Syringes and Disposables are provided sterile.

9. Performance Testing

Substantial equivalence between the subject device (Optistar Elite) and the predicate device (Optistar MR) can be demonstrated mostly through verification steps. The following steps were taken:

1. Evaluation of Conformity to Standards – The Optistar MR and the Optistar Elite both conform to recognized consensus standards, specifically:
   IEC 60601-1
   IEC 60601-1-2
   IEC 60601-1-4

2. Software Verification and Validation – as can be seen by reviewing the Safety and Effectiveness comparison chart, the software differences between the Optistar MR and the Optistar Elite do not impact the safety and effectiveness of the contrast media injector. They have been implemented as conveniences to the user. Software implemented for the Optistar Elite has been verified and validated.

   - Verification testing was accomplished through unit, integration, exploratory, and system level testing. Production equivalent software passed all acceptance criteria in the verification protocol.

   - Validation testing was performed by customers on production equivalent units in simulated clinical conditions. Based on the results, it can be concluded that the Optistar Elite software meets its intended use and meets defined customer needs when thoroughly assessed against the product's Customer Requirements.

3. Non-Software Verification

   - The product requirements were verified by reviewing the part (or assembly) drawing, bill of material, labeling and manuals, or other form of data. The Optistar Elite is mechanically and electrically equivalent to Optistar LE, and therefore documentation for Optistar LE was used to provide verification for the Elite.

   - When the Optistar MR was introduced, it was validated in a 1.5 Tesla environment, which represented the standard MR scanner found in imaging facilities at that time. Since then, MR scanners having a higher field strength have been introduced to the market. The Optistar LE injector has been tested with a variety of MR scanners from various manufacturers. These MR systems had magnetic field strengths up to 3.0 Tesla. In this environment, the injector performed as specified, delivering accurate volume, flow and pressures. The power consumption of the injector did not change when operating in this environment. The scanner manufacturers verified that the presence of the Optistar LE injector near the MR scanner did not interfere with the operation of the MR systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Dale Moore
Quality Manager
Mallinckrodt Inc., Liebel-Flarsheim Business
2111 East Galbraith Road
Cincinnati, OH 45237

Re: K073592
Trade/Device Name: Optistar Elite Injector System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II (two)
Product Code: DXT
Dated: April 11, 2008
Received: April 14, 2008

Dear Mr. Moore:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

K073592

510(k) Number (if known): **KXXXXX**

Device Name: **Optistar Elite Injection System**

Indications For Use:

The Optistar Elite Injection System is a contrast delivery system and is designed to inject MR contrast media and flushing solutions into a patient's vascular system to obtain diagnostic images when used with Magnetic Resonance Imaging equipment.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ______ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K073592