K984088

DEC - 6 1999

Liebel-Flarsheim
A MALLINCKRODT COMPANY

Optistar MR Injector System 510(k) Summary

November 4, 1998

Contact Name: Bridget Drake
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Proprietary Name: Optistar MR Injector System

Common Name: Injector System

Classification Name: Injector and Syringe, Angiographic

Predicate Device: Medrad Spectris MR Injection System (K935668)

Intended Use:

The Optistar MR Injector System is intended for injecting MR contrast agents and flushing solutions for the purpose of enhancing diagnostic imaging of humans.

Description:

The Optistar MR is a contrast delivery system that is designed to inject image enhancing contrast media into the vascular system of a human during an MRI (Magnetic Resonance Imaging) procedure.

The main components of the Optistar MR system are the console, power pack, and powerhead. The console resides in the control room of the MR suite, while the power pack and powerhead remain in the scanning room with the patient. The parameters of the injection, such as volume and flow rate are programmed by the operator using a touch screen on the console. The console is powered by AC line voltage at 110 Volts at 60 Hz. The console communicates with the 24 VDC powered powerpack which in turn supplies power and the injection parameters to the powerhead. The powerhead performs the injections by driving one or two lead screw rams. The rams push the plunger of a syringe

syringe, which expels fluid from the barrel of the syringe. The console, power pack and powerhead are discussed in greater detail below.

Powerhead: The powerhead provides a means for accepting and identifying a given syringe and then applying a force to the plunger of the syringe via a ram, which ejects contrast from the syringe. The powerhead communicates with the power pack in order to determine the flow rates and volumes designated by the user. This information is then relayed to the injector. The powerhead resides in the imaging room with the scanner.

Console: The console is the main user interface for the injector system. It allows the user to input the 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. The console resides in the control room of the MR imaging suite.

Power Pack: The power pack is the interface between the console and the powerhead. The power pack processes the information input by the user from the console and relays this information to the powerhead. The power pack also supplies the powerhead with DC voltage. Two batteries supply the power pack. The power pack resides in the imaging room with the scanner.

The system is designed to deliver two injections per procedure. It can deliver a single or dual phase contrast injection from a user filled syringe and then follow up with an injection of a flushing solution, such as saline. To accomplish this task the powerhead holds two syringes with the ability to inject both syringes. Two syringe sizes can be used with the Optistar MR system, a 60 ml size and a 25 ml size. In addition, a Y tubing set is used to transfer the contrast flushing solution to the patient. One short leg of the Y connects to the contrast filled syringe using a luer lock connector. The other short leg of the Y connects to the syringe with the flushing solution using a luer lock connector. The long single leg of the Y goes to the patient.

The system also includes a battery charger, which is used to recharge the 24 V batteries.

Substantial Equivalence:

A comparison chart is shown on the next page that compares the technological characteristics of the Optistar MR Injection System to the predicate device, the Spectris MR Injection System. The performance and effectiveness of the Optistar MR is substantially equivalent to the predicate device. The new injector safely and successfully injects MR contrast media at user specified flow rates and volumes in an MR environment. The primary differences from the predicate device lie in the area of user preference features. The differences do not adversely affect the safety or efficacy of the device. A summary of the testing that verified the technological characteristics of the Optistar MR follow shall follow the comparison chart.

Characteristic/ Feature	Spectris (predicate device) (K935668)	Optistar MR (new device)
Multiphasic Contrast Injections	2 phases per protocol	2 phases per protocol
Protocol Storage	20 protocols	20 protocols
Injection History	Stores last 5 injection results	Stores last 20 injection results
Scan Delay	00:00 - 00:59 minutes	00:00 - 00:59 minutes
Syringe System – A side	65 ml	60 ml or 25 ml
Syringe System – B side	65 ml	60 ml or 25 ml
Volume	1-63 in 1 ml increments	1-61 in 1 ml increments (60 ml syringe) 1-27 in 1 ml increments (25 ml syringe)
Flow Rate - Contrast	0.1 to 10 ml/sec in 0.1 ml/sec increments	25 ml syringe - 0.1 to 8.0 ml/sec in 0.1 ml/sec increments 60 ml syringe - 0.1 to 10 ml/sec in 0.1 ml/sec increments
Flow Rate – Flushing fluid	0.1 to 10 ml/sec in 0.1 ml/sec increments	25 and 60 ml syringe - 0.1 to 7.0 ml/sec in 0.1 ml/sec increments
Max Pressure Limit	300 psi	For 25 ml syringe – 200 psi(adjustable) For 60 ml syringe – 150 psi(adjustable)
Remote Start Switch	Yes	Yes
Mode for keeping a vein open	Yes	Yes – Drip Mode
Safety Stop Mechanism	Electrical stop when injection parameters are out of spec	Electrical stop when injection parameters are out of spec
User Interface Features		
Fill/expel control	push buttons on head	push buttons on head
Air detection	operator visual inspection	operator visual inspection
Programming injections	Touch screen display	Touch screen display
Injection status display	lights on top of power head	lights on top of power head
Materials	Plastics and nonferrous metals	Plastics and nonferrous metals
Anatomical sites	Contrast injection into venous system.	Contrast injection into venous system.
Intended use	The injection of MR contrast agents and flushing solutions for the purpose of enhancing diagnostic imaging of humans.	The injection of MR contrast agents and flushing solutions for the purpose of enhancing diagnostic imaging of humans.
Target population	Humans	Humans
Sterility	Disposables are provided sterile	Disposables are provided sterile

Performance Testing:

Performance testing was completed in order to verify that the Optistar MR Injector System was capable of achieving the specification parameters for the system as outlined in the substantial equivalence chart. Verification of the system's ability to accurately achieve these values validates the substantial equivalence claims. Injection performance was tested for accuracy of delivered flow rate, volume, pressure, drip mode and manual speeds.

Volume

Fluid delivery of an injector is characterized by the volume delivered and the flow rate. The volume delivered is the most critical parameter in that it has the greatest effect on image quality. During the testing, the volume delivered was accurately measured and compared to the volume programmed. Over the range of volumes programmed, the Optistar MR Injector system successfully delivered the programmed volume within the allowable specification accuracy. This held true regardless of syringe size (25 ml or 60 ml), injection side (A or B) or phase type (single or dual).

Flow Rate

The second most important variable in delivering fluid to a patient is flow rate. During the test injections, the time duration for an injection was recorded along with the volume delivered. The flow rate delivered was then calculated. Any injection accurately measured, that was not pressure limited, fell within the specified range. At higher flow rates, through a restricted orifice, the injector limits the pressure in the syringe by reducing the flow rate. In this case, the flow rate will not be achieved: however, the programmed volume will still be delivered.

Pressure

During an injection, the injector monitors pressure in order to determine if the injection should be pressure limited. An upper limit is set for each syringe type used in the injector, in order to avoid failure of the syringe. During a number of injections pressure was measured and compared to the pressure displayed by the injector. In all cases the injector was within the accuracy range

Drip Mode

Drip mode is used to keep a catheter or a vein open. The injector achieves this by administrating small increments of fluid over short time intervals. The injector allows the programming of the volume increment, a time interval and a flow rate. The performance of drip mode was evaluated by measuring the total volume delivered over a predetermined time period. Given a volume increment, a time interval, a flow rate and a measuring time period an expected volume was calculated and then compared to an actual measured volume to determine the accuracy for those parameters. Over the range of various drip mode parameters, the system fell within the specified accuracy range for all cases.

Manual Retract and Extend Speeds

The Optistar MR Injector has two speeds for manually moving the rams. By depressing either the forward or reverse key, the ram should move 1 ml/s. By pressing the accelerator key in combination with the forward or reverse key, the ram should move 5 ml/s. The tested speeds were within a specified accuracy range for both slow and fast speeds, for both A and B side, and for both 25 ml and 60 ml syringes.

Conclusion

The Optistar MR Injector System proved its ability to perform within its specified parameters. As a result, its performance is deemed acceptable and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 1999

Ms. Bridget Drake
Compliance Administrator
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Liebel-Flarsheim Business
2111 E. Galbraith Rd.
P.O. Box 156305
Cincinnati, OH 45215-6305

Re: K984088
Trade Name: Optistar MR Injector System
Regulatory Class: II
Product Code: DXT
Dated: September 3, 1999
Received: September 7, 1999

Dear Ms. Drake:

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 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). 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.

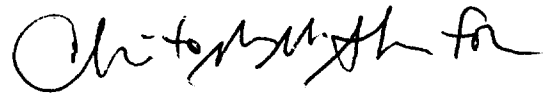
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4586. 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 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/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Acting Director
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K984088

DEVICE NAME: Optistar MR Injector System

INDICATIONS FOR USE:

The Optistar MR is designed to inject MR contrast agents and flushing solutions for the purpose of enhancing diagnostic imaging of humans. Contraindications for the use of this device are determined by the prescribing physician at the time of use based upon the contrast media package inserts. Not to be used in a magnetic field greater than 1.5 Tesla.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Witten

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K984088