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MEDRAD EnVision CT INJECTION SYSTEM 510(K) SUMMARY

October 29, 1999

Official Contact: Jan Dobscha, Senior Regulatory Affairs Coordinator
Medrad, Inc.
One Medrad Drive
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(412) 767-2400 ext. 3280

Classification: Injector with Syringe, Angiographic

Common/Usual Name: Powered Injector with Syringe

Proprietary Name: EnVision CT Injection System

Predicate Device: EnVision CT Injection System (K934086)

Medrad, Inc.
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Indianola, PA 15051-0780
(412) 767-2400

Device Description:

Technical Description:

The Medrad EnVision CT Injection System is a modified version of the EnVision CT Injector (K934086). It has the same indications for use and the same intended use as the predicate device. No changes to the fundamental scientific technology were made nor are any new risks introduced by this modification. The EnVision CT Injection System is a programmable, syringe-based fluid delivery system for delivery of contrast media during computed tomography procedures. Programming is achieved via a touch screen LCD display. No advanced scientific principles beyond those normally associated with electro-mechanical devices are employed.

The EnVision CT Injector is comprised of the three main components – Master Control Unit (MCU), Display Control Unit (DCU), Injector Head (HCU). The Medrad EnVision CT Injector System, like the predicate EnVision CT Injector System, uses a 125ml and 200ml Front Load Sterile Disposable Syringe. The only difference is that the modified Injector accommodates the use of an alternate 200ml contrast pre-filled syringe, and it now has an Imaging System Interface

- Master Control Unit (MCU) – is the "center" of the EnVision CT Injector System. Contained within the MCU is the microprocessor, system power supply, and ancillary ports for service access. Power comes into the MCU and is distributed to the remaining units. The DCU and Injector Head are connected to the MCU through various cabling. The MCU gathers information from the DCU and HCU, interprets the information, executes the injection, controls the head's plunger piston motor, and monitors injection feedback from the HCU. The microprocessor processes key and display information to and from the DCU, and stores and retrieves injection program and panel information from the user. It processes commands and formats data for the service port, monitors vital system status information and communications, and interacts with external imaging interfaces. It also controls the operation of an optional Remote DCU.

- Display Control Unit (DCU) (primary) - The is the main user interface and is controlled by a microprocessor. It is the main point of user data entry and display feedback data display.

components but keeps power supplied to all system microprocessors. The only change is that it now contains software for the imaging system interface. (See description below)

- Remote Monitor (a.k.a. Intelligent Hand Unit) - The purpose of the Remote Monitor is to allow the operator to interact with the Injector Head without being near the Head. It permits the operator to view two phases of the injector's programmed parameters and to control the injector's Start/Hold and Disarm functions. The Remote Monitor provides LED readouts to display Scan Delay, Injected Volume, Injection Duration, Phase, Flow Rate, and Volume information. It connects to the System Power Unit by means of an integral cord set. It can be placed up to 100 feet from the System Power Unit. The Remote Monitor has essentially been unchanged from the predicate device. The only change is that it now contains software for the imaging system interface. (See description below)

- Manual Startswitch - A hand-held push button handswitch, connected to the Injector Head via a cable, allows the operator to initiate, suspend, or resume a programmed injection.

- Imaging System Interface (ISI) - (Also known as Autolink) A small printed circuit board (pcb) that resides in the System Power Unit. The pcb acts as an interconnect card for the Injector Head and Remote Monitor, and provides an isolated interface connection between the Injector and CT Scanner. There is one input and one output to the operator. The input is composed of two signal lines and the output has three signal lines. All signal lines are fully isolated in order to provide protection to the Injector and CT Scanner. Physical connection to the CT Scanner is via a DB25 connector. The ISI pcb is controlled by the Remote Controller. An Injector System Interface software module was added to the Remote Controller software to effect this function. The Injector System Interface module receives inputs from CT Scanner which are used to initiate or stop an injection. It also controls outputs to the CT Scanner which are used to activate a scan. Throughout its processing, the Imaging System Interface software verifies the functionality of all input and output signals

Functional Features:

Except for the change to the Syringe Sensing and the addition of the Imaging System Interface, functionality has not changed. The following is a summary of the Injector's specifications.

Program	The user can program the injector with the following injection parameters: fluid volume, flow rate, injection duration, pause or pause/KVO, and scan delay.
Injection Profile	The user can program a sequence of one or more program phases, up to a maximum of 10, in which each phase delivers fluid according to the program parameters defined for that phase.
Pause	A command which can be programmed into the injection profile which causes the injector to stop for a programmed interval between phases. The pause duration can be set from 1 second to 10 minutes in one second increments.
Pause/KVO	Keep Vein Open (KVO) is an option that the user can specify for any PAUSE programmed into the injection profile. KVO causes the injection of fluid at a low average flow rate to keep the vein at the catheter site from clotting during a programmed "Pause". The KVO flow can be continuous or intermittent with an average flow rate of .01 ml/sec.
Hold	"Hold" allows the user to temporarily interrupt an injection. When the user enables the "Hold" function, the system remains armed, but the injection stops until the user cancels the hold function, whereupon the injection resumes from the point at which it was interrupted. The injector will remain in the "Hold" condition for a maximum of ten minutes, after which the unit disarms.

Scan Delay	"Scan Delay" is a function that the user can program into the injection profile to initiate a scan by a CT machine that has been properly connected to the Envision CT's relay closure. The "Scan Delay" interval begins simultaneously with the first phase of the injection profile. The interval duration can be set from 0 seconds to 99 seconds. A visible "Scan Delay" countdown clock, which shows the time remaining in 1 second increments, is located on the DCU. When the countdown clock reaches 0 an audible beep alerts the user.
Autofill	"Autofill" allows the user to load a specified amount of fluid into a syringe by actuating a control on the Injector Head. Once the "Autofill" control is activated the head will load the specified amount of fluid into the syringe without further operator interaction The user may select volumes of 25, 50, 75, 100 125, 150, 175, or 200 depending on the syringe size used. The range for the user selectable fill rate is 2ml/sec to 9.9ml/sec. The Autofill feature is non-functional when an alternate 200ml contrast prefilled syringe is installed.
Single/Multi Arm	The user can select one of two arming modes. "Single arm" allows the execution of a single injection profile after pressing the start switch. After the programmed injection has been completed, the unit disarms. "Multiple Arm" allows the programmed injection to be repeated without re-arming the injector. After completing its programmed injection, the injector remains in the armed state. The user can press the Start switch again to repeat the same programmed injection Repeated activation of the Start switch will deliver the programmed injection until there is insufficient contrast media in the syringe to complete a full injection. At this point, the injector will inform the user that there is insufficient volume for another injection.
Syringe Sensing	"Syringe Sensing" is a system on the injector head that determines which of the three compatible syringe sizes (125ml, 200ml or an alternate 200ml contrast prefilled syringe) is installed on the injector head, and also senses whether or not the syringe has been installed properly. The injector head "reads" coded slots molded into the flange of the syringe which tell the injector what size syringe has been installed. After determining the size of the syringe that has been installed, the injector adjusts its pressure, volume and flow characteristics accordingly. If the syringe has not been properly installed, the injector issues an error message on the DCU alerting the user that the syringe is not correctly installed.
Syringe Heater	The Syringe heater maintains the temperature of preheated contrast medium within the syringe while the syringe is attached to the Injector. The heater operating temperature is 87.8° to 105.8° F.
Safety Stop	All critical system functions are continuously monitored during an injection to insure that the actual injection values do not deviate from the programmed values beyond a specified limit. A microprocessor in the MCU and HCU constantly monitors the electrical functions of the injector system. The HCU monitors for over volume and over flow rate, and the MCU monitors for over volume and over flow rate, as well as pressure/stall and over-pressure. When the backup monitoring system detects one of these conditions, it will open a relay in the HCU to cut power to the piston motor and the injector system is placed in a maintenance state.

Retract Control — A control provided to return the piston to its fully retracted station. A single touch of a button is required to activate and complete this operation. This function is only operational when the syringe is detached from the injector system. The Syringe Sensing system detects whether or not a syringe is in place.

Imaging System Interface — An interface between the Injector and CT Scanner. Permits the operator to initate a scan sequence from the Injector, or to trigger an injection from the CT Scanner. This is a new feature, described in detail above.

Technological Characteristics

Feature	Medrad EnVision CT Injector with ISI & PPCM (Modified Device)	Medrad EnVision CT Injector (K934086) Predicate
Information Display	Monochrome LCD	Monochrome LCD
Programming Keys	Non-Dedicated Keys – Software Determined	Non-Dedicated Keys - Software Determined
Arming Modes	Single/MultiArm	Single/MultiArm
Multi-Phase	1 - 10 Phases per Injection	1 – 10 Phases per Injection
Protocol Storage Capability	50	50
Hold Capability	0 - 600 seconds	0 - 600 seconds
Scan Delay	0-99 seconds	0 - 99 seconds
Safety Stop Mechanism	Electrical Stop with a Software Backup System	Electrical Stop with a Software Backup System
Syringe System	200ml, 125ml, alternate 200ml	200ml, 125ml
Automatic Piston Retract	25 sec	25 sec
Volume Remaining Readout	LED	LED
Programmed Volume	1 to 125ml or 1 to 200 ml Depending on Syringe Size	1 to 125 ml or 1 to 200 ml Depending on Syringe Size
Autofill	Selectable – increments of 25ml for 125ml syringe; increments of 50 for 200ml syringe; inactive for alternate 200ml syringe	Selectable - increments of 25ml for 125ml syringe; increments of 50ml for 200ml syringe
Fill Rate	2 ml/sec to 9.9 ml/sec	2 ml/sec to 9.9 ml/sec
Flow Rate	Variable .1 ml/sec to 9.9 ml/sec	Variable .1 ml/sec to 9.9 ml/sec
Pause	Programmable 1 sec to 10 min	Programmable 1 sec to 10 min
KVO	Continuous or intermittent– AVG minimum flow rate of .01 ml/min	Continuous or intermittent– AVG minimum flow rate of .01 ml/min
Pressure Limit	Settable from 50 to 300 PSI	Settable from 50 to 300 PSI
Remote Start Switch	Yes	Yes
Imaging System Interface (aka Communicator)	Yes	No

Supporting Data:
Medrad has established, as part of its Quality System, design controls in compliance with FDA's Quality System Requirements. These design controls are applied to all Medrad product development processes and product design changes. These design controls were applied to the development of the EnVision CT Injector and meet the requirements of the FDA's QSRs.

As part of the design control a risk analysis was performed, and design verification and validation testing was conducted to support the conclusion drawn by the risk analysis.

Conclusion:

Test results concluded that the design specifications for the EnVision CT Injection System were met. The EnVision CT Injection System meets the applicable requirements of the following standards:

IEC 529 (IPX1) = Classifications of Degrees of Protection Provided by Enclosures
IEC 601-1, Amendments 1 and 2 = Medical Electric Equipment Part 1: General requirements for safety, 1. Collateral standard: Safety requirements for medical electrical systems
IEC 601-1-2 = Medical Electrical Equipment Part 1.2 Collateral standard: Electromagnetic Compatibility - Immunity Requirements and Tests
IEC 801-2 = ESD Immunity
IEC 801-3 = Radiated Immunity
IEC 801-4 = EFT/Burst Immunity
IEC 801-5 = Surge Immunity
UL 2601-1:1994 = Standard for Medical Equipment
CSA C22.2 No. 601.1-M90 = Medical Electrical Equipment Part 1: General Requirements for Safety

Therefore, it has been determined that the EnVision CT Injection System is substantially equivalent to the predicate device for its intended use when used as prescribed in the User Operation Manual.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 1999

Ms. Jan Dobscha
Sr. Regulatory Affairs Coordinator
Medrad, Inc.
One Medrad Drive
Indianola, PA 15051

Re: K993728
Trade Name: Medrad Envision CT Injection System
Regulatory Class: II
Product Code: DXT
Dated: October 29, 1999
Received: November 4, 1999

Dear Ms. Dobscha:

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
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MEDRAD®

INDICATION FOR USE

510(k) Number:_____

Device Name: Medrad Envision CT Injection System

Indications for Use/Intended Use:

The EnVision CT Injection System is a syringe-based fluid delivery system indicated for delivery of contrast media during computed tomography applications. It is intended to be used for the specific purpose of injecting intravenous contrast medium into the human vascular system for diagnostic studies in computed tomography.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Witten

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993728

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)