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**MEDRAD**<sup>®</sup>

## MEDRAD VISTRON CT INJECTION SYSTEM 510(K) SUMMARY

May 3, 1999

**Official Contact:** Jan Dobscha, Senior Regulatory Affairs Coordinator  
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One Medrad Drive  
Indianola, PA 15051  
(412) 767-2400 ext. 3280

**Classification:** Injector with Syringe, Angiographic

**Common/Usual Name:** Powered Injector with Syringe

**Proprietary Name:** Medrad Vistron CT Injection System

**Predicate Device:** Medrad Vistron CT Injection System (K982814)

**Device Description:**

Medrad, Inc.

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(412) 767-2400

### Technical Description

The Medrad Vistron CT Injection System is a programmable, syringe-based fluid delivery system for delivery of contrast media during computed tomography procedures. The Vistron CT Injector is a modified version of the Medrad Vistron CT Injector. 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 Vistron CT Injector is comprised of three main components - Injector Head, System Power Unit (SPU), and Remote Monitor (a.k.a. Intelligent Hand Unit). The Medrad Vistron CT Injector System, like the predicate Vistron 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.

- **SYSTEM POWER UNIT (SPU)** - The System Power Unit houses the injector's main power supply. It receives 110/220 VAC input and distributes power to the Injector Head via the Injector Head cable and to the Remote Monitor. The SPU has essentially been unchanged from the predicate device. The only change is that it now also contains circuitry for the imaging system interface. (See description below)
- **INJECTOR HEAD** - The Injector Head is the main user interface. It is the main point of user data entry and display feedback data. It contains the mechanical subsystem (motor and plunger piston) that delivers fluid through an attached syringe. It also consists of the syringe interface, position encoder, syringe position/size sensors, user display/control interface, electronic controls, and safety circuits. The syringe heat maintainer and the hand held startswitch connect externally to the head.

The Injector Head processes keyboard inputs from the hard keys on the control panel, Remote Monitor, or hand held startswitch. It displays injection parameters and operating information on the control panel's LEDs, and processes handswitch input. It also provides a standby switch which places the system in a standby mode; that is, it disables power to functional system 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, the functional specifications have not changed. The following is a summary of the Injector's specifications.

**Programmed Volume** - The volume of contrast medium delivered is settable for each phase of the injection profile. The range is 10 ml to 125 ml or 10 ml to 200 ml depending on the size of syringe used.

**Programmed Flow Rate** - The flow rate is the ratio of fluid volume delivered to the injection duration (ml/sec) and is settable, in 0.1 ml/sec increments, for each phase of the injection profile. The range is 0.1 ml/sec to 9.9 ml/sec.

**Pressure Limiting** - The system has a settable pressure limit. The range is 50 psi to 300 psi with increments of 50 psi. In the event of a pressure limit being reached, the injection will proceed at a reduced flow rate until the programmed volume has been delivered, unless a stall condition occurs. A stall condition will automatically terminate the injection. The user is alerted via audible beeps and an indicator light on the Injector Head control panel.

**Program Parameters** - The user can program the injector with fluid volume, flow rate, injection duration, pressure limit value, program phase/level, and scan delay parameters.

**Injection Profile** - The user can program a sequence of one or more program phases, up to a maximum of 4, in which each phase delivers fluid according to the program parameters defined for that phase.

**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, an audible beep is emitted and a message is displayed on the Injector Head and Remote Monitor.

**Scan Delay** - "Scan Delay" is a function that the user can program into the injection profile to indicate to the user that they should begin the scan. The "Scan Delay" interval begins simultaneously with the first phase of the injection profile. The interval duration can be set from seconds to 99 seconds. A visible "Scan Delay" countdown clock, which shows the time remaining in 1 second increments, is located on the Injector Head control panel and Remote Monitor. When the countdown clock reaches 0 an audible beep emitted from the Injector Head and Remote Monitor 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 200ml depending on the syringe size used. The fill rate is fixed at 2ml/sec. The Autofill feature is non-functional when an alternate 200ml 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, by flashing the Volume Remaining display, that there is insufficient volume for another injection. The operator is permitted to complete the injection with less than the programmed volume available in the syringe.

**Syringe Sensing** - "Syringe Sensing" is a system on the injector head that determines which of the two compatible Medrad 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. 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 Injector Head control panel 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 range 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 secondary microprocessor in the Injector Head constantly monitors the electrical signals of the injector system. It monitors for over-volume, over flow rate, and pressure/stall; a hardware comparator circuit monitors for over-pressure. When the backup monitoring system detects one of these conditions, it will open a relay 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 initiate a scan sequence from the Injector, or to trigger an injection from the CT Scanner. This is a new feature, described in detail above.

**Intended Use:** The Vistron 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.

**Technological Characteristics**

Feature	Medrad Vistron CT Injector with ISI & PPCM (Modified Device)	Medrad Vistron CT Injector (K982814) Predicate
Information Display	Large Colored LEDs	Large Colored LEDs
Programming Keys	Non-Dedicated Keys - Software Determined	Dedicated Function Keys
Multi-Phase	1 - 4 Phases per Injection	1 - 4 Phases per Injection
Arming Modes	Single/Multi Arm	Single/Multi Arm
Protocol Storage Capability	Stores last protocol used	Stores last protocol used
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
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
Volume Remaining Readout	LED	LED
Fill Rate	2 ml/sec to 9.9 ml/sec	2 ml/sec to 9.9 ml/sec
Flow Rate	Settable .1 ml/sec to 9.9 ml/sec (Settable for each injection during programming and during injection.)	Settable .1 ml/sec to 9.9 ml/sec (Settable for each injection during programming and during injection.)
Pressure Limit	Settable from 50 to 300 PSI	Settable from 50 to 300 PSI
Autofill	Fill rate fixed at 2 ml/sec. (Non-functional when PPCM is used.)	Fill rate fixed at 2 ml/sec
Retract Control	Yes	Yes
Imaging System Interface (AutoLink)	Yes	No
Remote Start Switch	Yes	Yes

**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 Vistron 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 Vistron CT Injection System were met. The Vistron CT Injection System meets the applicable requirements of the following standards: IEC 601-1, IEC 601-1-2, IEC 1000-4-6, IEC 1000-4-8, IEC 1000-4-11, IEC 1000-3-2, IEC 1000-3-3, IEC 529, UL 2601, and CSA C22.2 No. 601.1-M90. Therefore, it has been determined that the Vistron 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

JUL 21 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K991557  
Trade Name: Medrad Vistron CT Injection System  
Regulatory Class: II  
Product Code: DXT  
Dated: June 18, 1999  
Received: June 21, 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,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



INDICATION FOR USE

510(k) Number: \_\_\_\_\_

Device Name: Medrad Vistron CT Injection System

Indications for Use/Intended Use:

The Vistron 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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Orlyson M. So Callahan*

(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K991557

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)