

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

August 7, 1998

K982814

**Official Contact:** Jan Dobscha, Senior Regulatory Affairs Coordinator  
Medrad, Inc.  
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 EnVision CT Injection System (K934086)

**Device Description:**

Medrad, Inc.  
Medrad Drive  
15051-0790  
(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 EnVision 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 EnVision CT Injector System, uses a 125ml and 200ml Front Load Sterile Disposable Syringe.

- **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.
- **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.

- **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.

- **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.

### Functional Features:

- 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 0 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.
- 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 or 200ml) 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.

**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 (New Device)	Medrad EnVision CT Injector (K934086)
Information Display	Large Colored LED's	Monochrome LCD
Programming Keys	Dedicated Function Keys	Non-Dedicated Keys - Software Determined
Multi-Phase	1 - 4 Phases Per Injection	1 - 10 Phases Per Injection
Arming Modes	Single/Multi Arm	Single/Multi Arm
Protocol Storage Capability	Stores last protocol used	50 Protocols
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	200ml, 125ml
Programmed Volume	10 to 125 ml or 10 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	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 only)	Variable .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 25 to 300 PSI
Pause	No	Programmable - 1 sec to 10 min
KVO	No	Continuous or Intermittent - Avg minimum flow rate of .6 ml/sec
Autofill	Fill rate fixed at 2 ml/sec	Fill rate 2 ml/sec to 9 ml/sec in 1 ml/sec increments
Retract Control	Yes	Yes
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:**

The results of the risk analysis concluded that the modifications to the EnVision CT Injector did not introduce any new or additional risks relative to the use of this device. Testing also demonstrated that the Vistron CT Injection System met 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 safe and effective for its intended use when used as prescribed in the User Operation Manual.



OCT - 9 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K982814  
Trade Name: Medrad Vistron CT Injection System  
Regulatory Class: II  
Product Code: DXT  
Dated: September 11, 1998  
Received: September 14, 1998

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

Enclosure



INDICATION FOR USE

510(k) Number: K982814

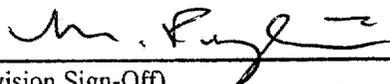
Device Name: Medrad Vistron CT Injection System

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)



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

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

Prescription Use              
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)