K991653

Summary of Safety and Effectiveness for the RyMed Technologies INVISION-PLUS™ Injection Ports

JUN 24 1999

submitted by:

RyMed Technologies, Inc.
3110 Blue Sage Drive
Woodward, OK 73801

Identification of a Legally Marketed Predicate Device

The RyMed Technologies INVISION-PLUS™ Injection Port Systems are substantially equivalent to Injection Port Systems manufactured by:

- ICU Medical, San Clemente, CA

The RyMed Technologies INVISION-PLUS™ Injection Port Systems are composed of either a Heparin Lock Injection Port, or a Y- Injection Port that contain a specialized two part valve made from medical grade Silicone material. The female luer housing, guide washer, and heparin lock are made from medical grade plastics. The valve provides excellent fluid Flow Rates, low Priming Volumes, and reseals after extended use.

See appendix 1 for diagram and fluid flow path through valve.

Intended Use

The RyMed Technologies InVision-Plus™ Injection Port Systems are intended for single patient use in intravenous and blood administration sets without need for needles, thus eliminating the potential for needle-stick injuries during use.

Summary of Performance Data

Test	Acceptance Criteria	RyMed InVision-Plus™
Fluid reflux	< 0.015ml	Met criteria
Fluid flow rate w/18 ga catheter	= > 1.30 mL/second	Met criteria
Priming volume	< 0.04 mL	Met criteria
Reseal after IV Push (when using normal saline)	Must reseal after 96 hours use	Met criteria
Reseal after IV Drip (when using normal saline)	Must reseal after 96 hours use	Met criteria
Reseal (when using blood)	Must reseal after 24 hours use	Met criteria
Reseal (when using lipids)	Must reseal after 48 hours use	Met criteria

Summary of Technological Characteristics

Feature	Submitted Device	Predicate Device
Trade Name	INVISION-PLUS™ Injection Port	ICU Medical CLC2000™
Manufacturer	RyMed Technologies	ICU Medical, Inc
510 Number	To be determined	K973167
Intended Use	Intravenous and blood administration	Intravenous and blood administration
Disposable for single patient use	Yes	Yes
Fluid Reflux	0.012 mL	0.032 mL
Flow Rate	1.47 mL / sec. *	2.57 mL/ sec.
Priming Volume	0.0333 mL	0.0735 mL
Heparin Lock Injection Ports	Yes	Yes
J Loop Tube Extension	Yes	Yes
T Connector/ Tube Ext.	Yes	Yes
IV Administration Sets	Yes	Yes
Packaging	Peel pouch or rigid blister pack	Blister pack
Sterilization	Gamma radiation	Unknown, believed to be ETO
Non-pyrogenic	Yes	Yes
Materials	Polycarbonate; silicone rubber; polyethylene/polypropylene, stainless steel	Polycarbonate, glass filled polyester, stainless steel, silicone rubber

* Flow rate acceptance criteria was established at a minimum of 1.30 mL per second. This is the flow rate for an 18 ga. Catheter. 18 ga. Catheters can be used for all I.V. fluid administration (I.V. solutions, lipids, and blood products). Fluid flow rates greater than an 18 ga. Catheter are not required for I.V. Administration.

The INVISION-PLUS™ Injection Port Systems are substantially equivalent to the predicate device. Extensive bench testing of both devices has demonstrated this. The recirculating blood contact materials of the device have been carefully selected for their long history of biocompatibility and have been tested to assure that they meet the requirements of ISO 10993-1.

We believe that the INVISION-PLUS™ Injection Port Systems are safe and effective and perform as well as or better than the predicate device. . The INVISION-PLUS™ has been designed and developed utilizing design control methods in compliance with the GMP. The INVISION-PLUS™ will be manufactured per specifications and under Good Manufacturing Practices by an ISO 9000 certified manufacturer to ensure the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 1999

Mr. Al Weisenborn
RyMed Technologies, Incorporated
19526 East Lake Drive
Miami, Florida 33015

Re: K991653
Trade Name: InVision-Plus™ Injection Port Connector System
Regulatory Class: II
Product Code: FPA
Dated: May 12, 1999
Received: May 13, 1999

Dear Mr. Weisenborn:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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" (21 CFR 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/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Page 1 of 1

510(k) Number (if known): Not assigned

Device Name InVision-Plus™ Injection Port Connector System

Indications for Use:

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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)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991653