RyMed TECHNOLOGIES, INC.

K093489

510 (k) Summary

JUL 2 9 2010

Date Prepared [21 CFR 807.92(a)(1)]

Revised July 2, 2010

Submitter's Information [21 CFR 807.92(a)(1)]

This 510(k) is being submitted by a Joseph Azary (Regulatory / Quality Consultant) on behalf of RyMed Technologies, Inc. Joseph Azary can be contacted by telephone at (203) 922-0105 or fax at (203) 922-0130. Mailing address: 80 Shelton Technology Center, Shelton, CT 06484.

RyMed Technologies, Inc. is located at 6000 William Cannon Drive Building B, Suite 300, Austin, TX 78749. RyMed Technologies, Inc. is registered with FDA under Establishment Registration# 3005951712.

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade name: InVision-Plus® CS™ with Neutral Advantage™ Technology

Common / Classification Name: Intravascular Administration Set

Classification: This device falls under the responsibility of the Division of General Hospital Devices. Class II, Product Code: FPA, 21 CFR 880.5440

Predicate Device [21 CFR 807.92(a)(3)]

The following predicate devices have been identified:

- RyMed Technologies InVision-Plus™ Injection Ports – K991653

The subject device is similar to the RyMed Technologies InVision-Plus™ Injection Ports with regard to length, diameter, cross section, intended use, sterility, packaging, and flow rate.

The main difference

is the RyMed Technologies InVision-Plus® CS™ with Neutral Advantage™ Technology Injection Port Systems has a septum containing silver and chlorhexidine, and the spike body contains silver ions. The similarities and differences between the subject device and the untreated predicate device are outlined in Appendix 1.

- Baxter V-Link Antimicrobial Luer Activated Device – K081289

The subject device is similar to the Baxter V-Link Antimicrobial Luer Activated Device except the subject device contains silver and chlorhexidine on the septum as well as silver in the fluid path.

- ARROWg^{+}ard Blue Plus™ Multi-Lumen Central Venous Catheter – K993691

The subject device is similar to the ARROWg^{+}ard Blue Plus™ Multi-Lumen Central Venous Catheter in that it contains both silver ions and chlorhexidine acetate.

- Bard Intravenous Power Injector Extension Set – K090134

The subject device is similar to the Bard Intravenous Power Injector Extension Set in that it is rated for a maximum pressure of 325 psi and flow rate of 10 mL/sec.

Description of the Device [21 CFR 807.92(a)(4)]

RyMed's InVision-Plus® CS™ with Neutral Advantage™ Technology features pronounced intraluminal catheter fluid pathway protection using a combination of ten mechanical design features incorporated specifically for patient protection. The Neutral Advantage™ Technology features include a smooth swabbable septum surface, septum seal integrity with no gaps or openings, a double microbial physical barrier, straight-through fluid pathway, zero dead space, zero fluid displacement, low priming volume, 100% effective blood clearing, saline-only flush option and no clamping sequence or positive pressure syringe technique required.

The RyMed Technologies InVision-Plus® CS™ with Neutral Advantage™ Technology 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.

The RyMed Technologies InVision-Plus® CS™ with Neutral Advantage™ Technology Injection Port contains silver ions and chlorhexidine, which are intended to inhibit the growth of microorganisms on the treated surfaces of the device, which include the septum and the fluid path.

The RyMed Technologies InVision-Plus® CS™ with Neutral Advantage™ Technology Injection Port has been shown to be effective for 7 days against the following microorganisms: *Acinetobacter baumannii*, Methicillin-resistant *Staphylococcus aureus*, *Staphylococcus aureus*, *Escherichia coli*, *Candida albicans*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Staphylococcus epidermidis*.

The subject device is not intended to treat existing infections. The device is not intended to have any effect on contaminated infusion solutions.

Correlation between in vitro antibacterial activity and any clinical effectiveness has not been tested.

The InVision-Plus® CS™ with Neutral Advantage™ Technology Injection Port Systems may be used with low pressure power injectors having a maximum pressure of 325 psi and a maximum flow rate of 10 mL/sec.

The device is offered in the following configurations:

- Stand alone connector
- Administration Sets
- Stopcocks

The subject device is composed of materials that have been successfully and safely used in medical devices including the predicate devices. The materials used in the subject device have been subjected to and passed biocompatibility testing.

The subject device may be used with low pressure power injectors having a maximum pressure of 325 psi and a maximum flow rate of 10 mL/sec. When used with a low pressure power injector, the subject device must be secured with other devices rated for pressures up to 325 psi with a luer lock connection.

The subject devices are sterile single-use devices.

Intended Use [21 CFR 807.92(a)(5)]

The RyMed Technologies InVision-Plus® CS™ with Neutral Advantage™ Technology 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.

The RyMed Technologies InVision-Plus® CS™ with Neutral Advantage™ Technology Injection Port contains silver ions and chlorhexidine, which are intended to inhibit the growth of microorganisms on the treated surfaces of the device, which include the septum and the fluid path.

The RyMed Technologies InVision-Plus® CS™ with Neutral Advantage™ Technology Injection Port has been shown to be effective for 7 days against the following microorganisms: *Acinetobacter baumannii*, Methicillin-resistant *Staphylococcus aureus*, *Staphylococcus aureus*, *Escherichia coli*, *Candida albicans*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Staphylococcus epidermidis*.

The subject device is not intended to treat existing infections. The device is not intended to have any effect on contaminated infusion solutions.

Correlation between in vitro antibacterial activity and any clinical effectiveness has not been tested.

The InVision-Plus® CS™ with Neutral Advantage™ Technology Injection Port Systems may be used with low pressure power injectors having a maximum pressure of 325 psi and a maximum flow rate of 10 mL/sec.

Technological Characteristics [21 CFR 807.92(a)(6)]

The physical and mechanical design of the subject device is identical to the RyMed predicate device (K991653). The only difference in the subject device relative to the RyMed predicate device is that the septum is treated with silver and chlorhexidine, and the fluid path is treated with silver. The predicate devices cleared under K081289 and K993691 contain silver and silver/chlorhexidine, respectively. The predicate device cleared under K090134 is rated for use with low pressure power injectors having a maximum pressure of 325 psi and a maximum flow rate of 10 mL/sec.

Performance Data [21 CFR 807.92(b)(1)]

The subject device has been subjected to and passed a standard battery of biocompatibility assays per ISO 10993. Additional testing included microbial ingress and various physical and mechanical tests to assure seal integrity of the septum.

Conclusion [21 CFR 807.92(b)(3)]

The differences between the subject device and predicate devices are minor; it is therefore concluded that the subject device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

RyMed Technologies, Incorporated
C/O Mr. Joseph M. Azary
Senior Regulatory Consultant / Quality Systems Manager
Orchid Design
80 Shelton Technology Center
Shelton, Connecticut 06484

JUL 29 2010

Re: K093489
Trade/Device Name: InVision-Plus®CS™ with Neutral Advantage™ Technology
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: July 2, 2010
Received: July 6, 2010

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

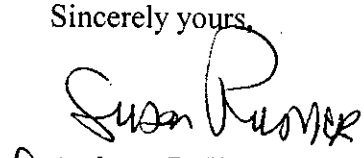
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093489

Indications for Use

JUL 2 9 2010

510(k) Number (if known):

Device Name: InVision-Plus® CS™ with Neutral Advantage™ Technology

Indications For Use:

The RyMed Technologies InVision-Plus® CS™ with Neutral Advantage™ Technology 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.

The RyMed Technologies InVision-Plus® CS™ with Neutral Advantage™ Technology Injection Port contains silver ions and chlorhexidine, which are intended to inhibit the growth of microorganisms on the treated surfaces of the device, which include the septum and the fluid path.

The RyMed Technologies InVision-Plus® CS™ with Neutral Advantage™ Technology Injection Port has been shown to be effective for 7 days against the following microorganisms: *Acinetobacter baumannii*, Methicillin-resistant *Staphylococcus aureus*, *Staphylococcus aureus*, *Escherichia coli*, *Candida albicans*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Staphylococcus epidermidis*.

The subject device is not intended to treat existing infections. The device is not intended to have any effect on contaminated infusion solutions.

Correlation between in vitro antibacterial activity and any clinical effectiveness has not been tested.

The InVision-Plus® CS™ with Neutral Advantage™ Technology Injection Port Systems may be used with low pressure power injectors having a maximum pressure of 325 psi and a maximum flow rate of 10 mL/sec.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

7/28/10

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093489