

AUG 23 1999

RD MEDICAL

MANUFACTURING, Inc.
Culebra, P.R.

K 992104

Abbreviated 510(k)

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Proposed Device: PARSET® I.V. Administration Set, Vented/Non-vented, one injection site, 80 in., Latex Free.

8. 510(k) Summary

Submitted by:

RD Medical Manufacturing, Inc., PO Box 899, Calle Escudero Final, Bo. Fulladosa, Culebra, Puerto Rico, 00775. *Contact:* Carlos A. Rodríguez-García, Ph.D., Product Development Director.

Date of Summary:

June 18, 1999

Trade Name of Proposed Device:

PARSET® I.V. Administration Set, Vented/Non-vented, one injection site, 80 in., Latex Free

Common Name:

Infusion Set

Classification Name:

Intravascular Administration Set (§880.5440).

Predicate Device:

Baxter Vented Solution Set, Catalog # 2C5419s.

Description of Proposed Device:

The proposed administration set will be used for intravascular administration of fluids and medication. The proposed device contains a vent with filter such that it can be used with non-collapsible fluid containers. The vent also has a cap to close the vent when using a collapsible fluid container (e.g., IV bag) which does not require a vent. The proposed device also contains an injection site 8 in. from the distal luer slip connector.

Intended Use:

The intended use of the proposed device is for the intravascular administration of fluids and medication by trained health care personnel. The administration of fluids is achieved through gravity from collapsible or non-collapsible fluid containers through a venipuncture device (not included in the proposed device).

Summary of Technological Characteristics of Proposed Device to Predicate Device

The proposed device is composed of the same type of components and intended use of the predicate device. The differences between the proposed and predicate devices include

Proposed Device: PARSET® I.V. Administration Set, Vented/Non-vented, one injection site, 80 in., Latex Free.

a latex-free injection site: composed of polyisoprene, a synthetic polymer; vent cap, to use the set with fluid bags; drops / mL, which is 20 for the proposed device and 10 for the predicate device. The predicate device contains a slide clamp, which is a feature that does not add any functional advantage.

The results of the biocompatibility tests and chemical tests, conducted as per ISO 10993-1 and ISO 8536-4 respectively, indicate that the polyisoprene used in the injection site is well within the safe operational limits for the intended use of the proposed device. The product performance, illustrated by the flow rate data, indicates that the installation of the cap is a beneficial feature that complies with the flow rate specification in ISO 8536-4.

Discussion of Non-clinical Tests

Testing of the proposed device was conducted as per the Recognized Consensus Standards:

- ISO 8536-4: 1987, Infusion equipment for medical use - infusion sets for single use, gravity feed
- ANSI/AAMI/ISO 10993-1, Guidance on selection of tests
- ANSI/AAMI/ISO 11607: 1997, Packaging for terminally sterilized products
- ANSI/AAMI/ISO 11137: 1994, Sterilization of health care products- requirements for validation and routine control- radiation sterilization.

The results of the tests conducted for compliance to Recognized Consensus Standards have been provided. All data indicate that the proposed administration set meets or exceeds all functional requirements and therefore supports the suitability of the proposed device for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 23 1999

Carlos A. Rodriguez-Garcia, Ph.D.
Product Development Director
RD Medical Manufacturing Incorporated
Calle Escudero Final, Bo Fulladose
Cuebra, Puerto Rico 00775

Re: K992104
Trade Name: Parset, Model A10001E
Regulatory Class: II
Product Code: FPA
Dated: June 18, 1999
Received: June 22, 1999

Dear Dr. Garcia:

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.

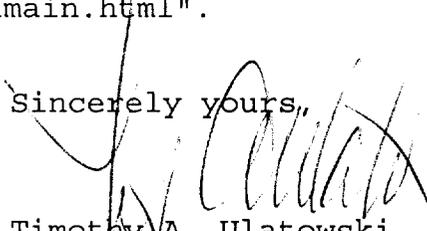
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

Page 2 - Dr. Garcia

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

510(k) NUMBER (IF KNOWN): K992104

DEVICE NAME: PARSET I.V. Administration Set Vented/Non-Vented, One Injection Site, 80 in., Latex Free

INDICATIONS FOR USE:

The device is used to supply medication and fluids intravascularly to patients through a needle or catheter inserted into the vein.

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

Concurrence of CDHR, Office of Device Evaluation (ODE)

Prescription Use /
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2)

Rafaela Curran

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992104