K092905

510(k) Summary

MAR - 4 2010

Contact Person: Elaine Duncan

Paladin Medical Inc.
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Brand Name: Analytica AutoStart Burette

Common Name: In-Line Burette

Classification Name: (21CFR 880.5540) Set, Administration, Intravascular

Product Code: FPA

Predicate Device: Tuta Healthcare In-Line Burette 150mL (K023595)

Date Prepared: 31 August 2009

Device Description: The AutoStart Burette is an in-line burette used for intravenous administration of fluids (either gravitational or via an infusion pump) from a container to a patient's vascular system through a cannula inserted into a vein. This is a sterile, single-use device.

The device is fitted with a float system which that allows the primary infusion to restart following addition to and dispensation of medication from the burette. There is no need to manually restart the infusion as is the case with conventional in-line burettes.

Indications for Use: Administration of fluids from a container to a patient's vascular system through a cannula inserted into a vein.

Summary of Basis for Substantial Equivalence:

The Analytica AutoStart Burette is substantially equivalent to the Tuta Healthcare In-Line Burette (K023595). Equivalence is based on equivalence of indications, design features and properties and supported by compliance with an FDA Guidance and an FDA recognized performance standard.

With the exception of the AutoStart flotation feature, both the AutoStart Burette and the predicate device have:

- **Identical indications for use**

  Both devices are indicated to be used in the administration of fluids from a container to a patient's vascular system through a cannula inserted into the vein.

- **Equivalent materials and components**

  Both devices are manufactured from medical grade polymers.

- **Equivalence of operation**

  Both devices are 150mL capacity, graduated, flow regulated in-line burettes.

The AutoStart Burette complies with *ISO 8536-5:2004 Infusion equipment for medical use Part 5 – Burette infusion sets for single use, gravity feed* – the FDA recognized safety and performance standard for these devices.

Risk assessment has been performed in conformance with ISO 14971:2007 and there are no significant new safety concerns raised by the design of the AutoStart Burette.

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

MAR - 4 2010

Analytic PTY, Limited
C/O Ms. Elaine Duncan
President
Paladin Medical, Incorporated
P.O. Box 560
Stillwater, Minnesota 55082

Re: K092905
Trade/Device Name: Analytica AutoStart Burette
Regulation Number: 21CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: February 8, 2010
Received: February 12, 2010

Dear Ms. Duncan:

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

510(k) Number (if known):

Device Name: Analytica AutoStart Burette

Indications for Use:

Administration of fluids from a container to a patient's vascular system through a needle catheter inserted into a vein.

Prescription Use __X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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