K030813

MAY 3 0 2003

3/4/03
PRIMARY CARE SOLUTIONS, INC
510(K) SUMMARY

Applicant Name/Address	PRIMARY CARE SOLUTIONS, INC. 40420 Free Fall Ave. Zephyrhills, FL 33542
Contact:	Ron Maddix Vice President, Marketing & Sales
Phone: Fax:	813-779-7226 813-715-4084
Trade Name:	Primary Care Solutions Prefilled 10cc and Prefilled 30cc Inflation Syringes with Sterile Water Catalog numbers 1010 and 1030 respectively
Establishment Reg. No.	1066336
Manufacturing Facility:	PRIMARY CARE SOLUTIONS, INC 40420 Free Fall Ave. Zephyrhills, FL 33542
Sterilization Facility:	FOOD TECHnology Service, Inc. 502 Prairie Mine Road Mulberry, FL 33860
Classification Name:	Syringe, Balloon Inflation
Class:	II
Reason for Application:	New Devices to Primary Care Solutions, Inc.
Predicate Devices:	K943836 – Pre-Filled 10cc Inflation Syringe with Sterile Water Orion Medical Products, Inc. Wheeling, IL 60090
Device Description:	The device is a 10cc and 30cc syringe pre-filled with USP purified water and gamma irradiated. The syringe is produced using polypropylene for the device barrel and plunger and pharmaceutical grade latex free rubber for both the plunger gasket and syringe tip cover.
Intended Device Use:	The 10cc and 30cc pre-filled syringes are intended to be used for foley catheter balloon inflation. The intended use of the device is identical to that of the predicate device and other similar devices in the market. The syringe is employed by connecting the syringe tip to the valve on the side arm of foley catheter and forcing sterile water through a lumen into the balloon for inflation.

Material Comparison to Predicate Device:	The predicate device contains exactly the same material components as the pre-market notice subject device as indicated in the device description summary above.
Compliance with special controls:	No applicable mandatory performance standards or special controls exist for these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Ron Maddix
Vice President, Marketing & Sales
Primary Care Solutions, Incorporated
40420 Free Fall Avenue
Zephyrhills, Florida 33542

Re: K030813
Trade/Device Name: Primary Care Solutions Pre-Filled 10cc and Pre-Filled 30cc Balloon Inflation Syringe with Sterile Water
Regulation Number: 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZL
Dated: March 4, 2003
Received: March 14, 2003

Dear Mr. Maddix:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 1 of 1

510(K) Number: K030813

Device Name: Primary Care Solutions Pre-Filled 10cc and Pre-Filled 30cc Balloon Inflation Syringe with Sterile Water

Indications For Use: A sterile water pre-filled syringe for use in inflating foley catheter balloon

(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

510(k) Number: K030813