U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(smw)
FOLDER:	K030813 - 43 pages
COMPANY:	PRIMARY CARE SOLUTIONS, INC. (PRIMCARESOLU)
PRODUCT:	CATHETER, RETENTION TYPE, BALLOON (EZL)
SUMMARY:	Product: PRIMARY CARE SOLUTIONS PREFILLED 10CC AND PREFILLED 30CC INFLATION SYR
DATE REQUESTED:	Aug 24, 2015
DATE PRINTED:	Aug 24, 2015
Note:	Printed

 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

MAY 3 0 2003

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2003

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
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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

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

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 14, 2003

PRIMARY CARE SOLUTIONS, INC.
40420 FREE FALL AVE.
ZEPHYRHILLS, FL 33540
ATTN: RON MADDIX

510(k) Number: K030813
Received: 14-MAR-2003
Product: PRIMARY CARE SOLUTIONS PREFILLED 10CC AND PREFILLED 30CC INFLATION

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at http://www.fda.gov/oc/mdufma).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

K073813

510(K) NOTIFICATION

PRIMARY CARE SOLUTIONS PRE-FILLED 10CC SYRINGE AND 30 CC SYRINGE WITH STERILE WATER

5K3

HO II 25

March 4, 2003

FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
510(K) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Re: 510(K) Notification

To Whom It May Concern:

In accordance with Section 510(K) of the Federal Food, Drug and Cosmetic Act, Primary Care Solutions, Inc. is submitting notification of its intent to manufacture and introduce into commercial distribution a Pre-Filled 10cc inflation syringe and a Pre-filled 30cc inflation syringe both containing sterile water.

Primary Care Solutions' Pre-filled 10cc and Pre-filled 30cc inflation syringes with sterile water are intended to be used for balloon inflation. These devices are not intended for wound irrigation or IV administration. The intended use of these devices is the same as a similar device currently in the market which will be referenced in the 510(K) notification attached hereto.

Primary Care Solutions, Inc. is not making any new claims for its Pre-filled 10cc and Pre-filled 30cc inflation syringes with sterile water. The intended use is the same as similar devices currently in the market.

As you review our notification, please contact the undersigned with any questions that you may have.

Thank you.

Sincerely,

Ronald L. Maddix

Ronald L. Maddix
Vice President, Marketing & Sales

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
Compliance with special controls:	No applicable mandatory performance standards or special controls exist for these devices.

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DEVICE DESCRIPTION

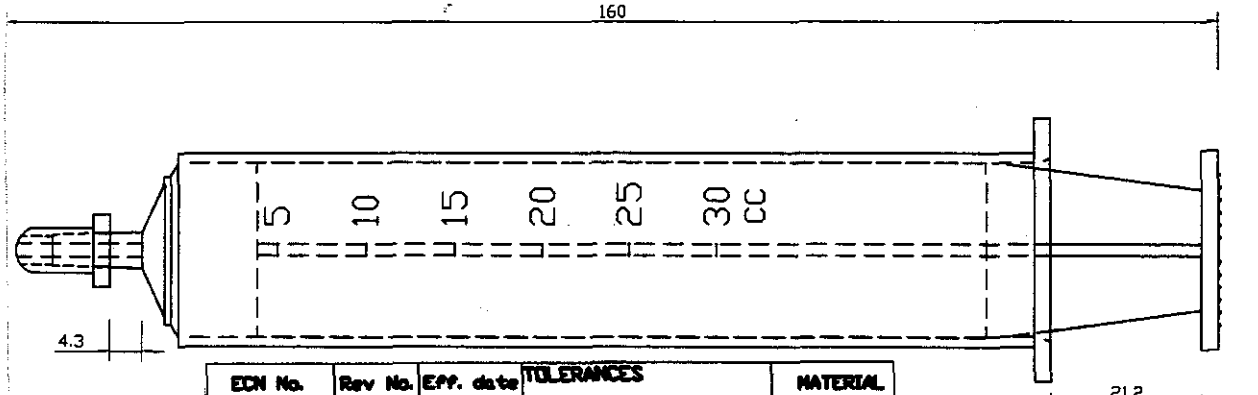
The subject device is a 10cc Pre-filled and a 30cc pre-filled syringe produced using polypropylene for the device barrel and plunger and pharmaceutical grade latex free rubber for the plunger gasket and syringe tip cover. The device is filled with USP purified water.

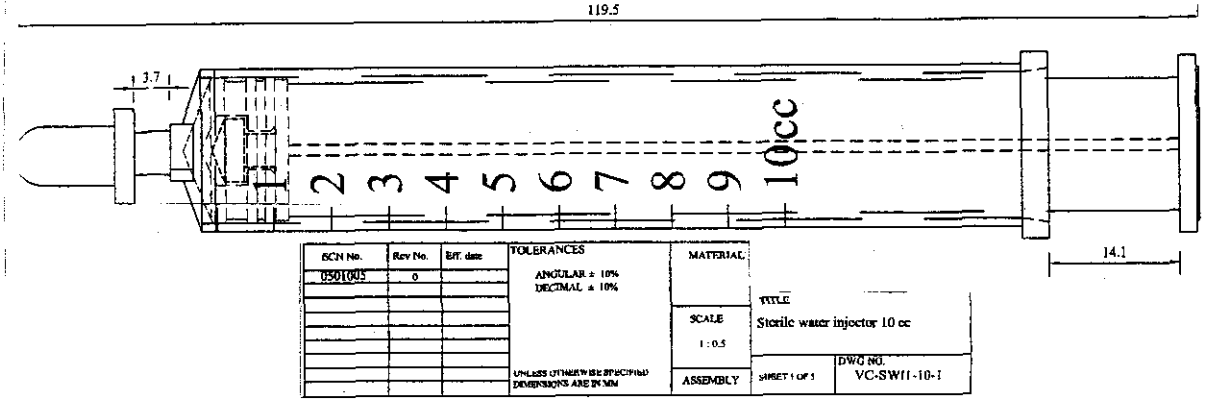
DEVICE SPECIFICATIONS

Device specifications are as follows:

It is Primary Care Solutions, Inc.'s intent to market 10cc and 30cc Inflation syringes with Sterile Water for catheter balloon inflation. The syringe barrel and plunger are produced from polypropylene and the plunger gasket and tip cover are produced using pharmaceutical grade synthetic rubber (latex free). The syringe is filled with USP purified water and gamma irradiated to render the water sterile. The syringe is latex free.

Physical characteristics reflect gradations 1 through 10 incrementally on the 10cc syringe and 5 through 30 in increments of 5 on the 30cc syringe. Drawings for each of the products are as follow:





INDICATIONS FOR USE/LABELING

Primary Care Solutions' Pre-filled syringes with sterile water are intended for use in balloon inflation. These devices are not intended for wound irrigation or injection. The intended use of the device is the same as the intended use for similar devices currently in the market, reference Orion Medical Products, 510(K) number K943836.

DEVICE LABELING

Contents Sterile Water
To Inflate Catheter Only
Connect Syringe Tip
Directly to Valve
Not for Injection

Primary Care Solutions is not making any claims for Pre-filled 10cc and 30cc inflation syringes that differ from the claims on the predicate device.

PREDICATE DEVICE/LABELING

Primary Care Solutions' Pre-filled 10cc Inflation Syringe and 30cc Inflation Syringe with Sterile Water are both similar to Orion Medical Products 10cc Inflation Syringe with Sterile Water and the components are similar to the components found in the Orion predicate device Ref. 510(K) K943836 whose label is as follows:

Sterile – For Single Use Only
Pre-Filled Syringe With Sterile Water
Catalog 3001
10ML Volume
For Balloon Inflation Only
Not For Use on Wounds
Not For Injection

COMPARISON TABLE

Primary Care Solutions is not making any new claims for Pre-filled 10cc and 30cc Inflation Syringe with Sterile Water. Listed below are the materials currently used in both companies' products:

	Primary Care Solutions	**Orion Medical Products**
Syringe Barrel	Polypropylene	Polypropylene
Syringe Plunger	Polypropylene	Polypropylene
Plunger Gasket	Black Pharmaceutical Grade, Synthetic Rubber (Latex Free)	Black Pharmaceutical Grade Synthetic Rubber (Latex Free)
Tip Cover	Same as Gasket	Same as Gasket

MANUFACTURING

Primary Care Solutions' 10cc Inflation Syringe and 30cc Inflation Syringe with Sterile Water will be filled with USP Purified water. The syringe itself is purchased as a raw material. The filling and packaging production will take place at the following location:

Primary Care Solutions, Inc.
40420 Free Fall Ave.
Zephyrhills, FL 33542

STERILIZATION

Sterilization will accomplished by:

(b)(4)

Primary Care Solutions, Inc. has selected Gamma Irradiation as the means of sterilizing its device and has

(b)(4)

With respect to sterilization, Primary Care Solutions, Inc. used the following reference to determine the Validation protocol and procedures:

(b)(4)

BIOCOMPATIBILITY ASSESSMENT

All materials used in this product are identical to the legally marketed predicate device. Biocompatibility study results are on file with applicant.

STATEMENT OF SAFETY AND EFFICACY

Primary Care Solutions, Inc. certifies that in accordance with the Safe Medical Device Act of 1990, it maintains on file all safety and effectiveness data regarding this device.

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 CFR 807.87j)

I certify that, in my capacity as Vice President of Marketing and Sales of Primary Care Solutions, Inc., I believe to the best of my knowledge that all data and information submitted in this premarket notification are ~~truth~~ful and accurate and that no material has been omitted.

Ronald L. Maddix

Ronald L. Maddix

3/11/03

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Avenue
Rockville, MD 20850

Date: May 28, 2003

From: Viola Hibbard

Subject: K030813

To: The Record

MEMORANDUM OF TELEPHONE CONVERSATION

(b)(4)

[redacted]

Hibbard, Viola

From: Rmatpar@aol.com
Sent: Tuesday, May 27, 2003 3:58 PM
To: VSH@CDRH.FDA.GOV
Cc: Sbhpcs@aol.com; NRuedt@aol.com
Subject: (no subject)

Viola,

(b)(4)

Thank you for your consideration and I am hopeful that you will agree with me. Please let me know.

Regards,

Ron Maddix

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K030813

Reviewer: Viola Hibbard

Division/Branch: DAGID/GHDB

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

Product To Which Compared (510(K) Number If Known): Pre-Filled Inflation Syringe with Sterile Water, Orion Medical Products, Inc. (K943836)

	YES	NO	
1. Is Product A Device	X		If **NO** = Stop
2. Is Device Subject To 510(k)?	X		If **NO** = Stop
3. Same Indication Statement?	X		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5. Same Technological Characteristics?	X		If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

1. Intended Use: The pre-filled syringes with sterile water are intended for use in inflating Foley catheter balloons.

2. Device Description: See SE Memo dated 5/27/03

MEMO TO THE RECORD
510(K) REVIEW

K030813

DATE: 05/27/03 OFFICE: HFZ-480
FROM: Viola Hibbard DIVISION: DDIGD/GHDB

COMPANY NAME: Primary Care Solutions, Inc.
DEVICE NAME: Primary Care Solutions Pre-filled 10cc and Pre-filled 30cc Inflation Syringes with Sterile Water

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

NARRATIVE DEVICE DESCRIPTION

1. SUMMARY DESCRIPTION OF THE DEVICE UNDER REVIEW:

The devices are 10cc pre-filled and 30cc pre-filled syringes using polypropylene for the device barrel and plunger and pharmaceutical grade latex free rubber for the plunger gasket and syringe tip cover. The device is filled with USP purified water.

Physical characteristics reflect gradations 1 through 10 incrementally on the 10cc syringe and 5 through 30 increments of 5 on the 30cc syringe.

The devices are intended for use and distribution by Kit Packers and not the end user. The devices are packaged in polybags and cartons and sterilized. This information was obtained from the sponsor via telephone.

2. INTENDED USE:

The pre-filled syringes with sterile water are intended for use in inflating Foley catheter balloons.

3. DEVICE DESCRIPTION:
   A. Life-supporting or life-sustaining: No
   B. Implant (short-term or long-term): No
   C. Is the device sterile? Yes
      If yes, is sterility information provided? Yes, see page 10.
   D. Is the device for single use? Yes
   E. Is the device for prescription use? Yes
      If yes, is prescription labeling included? Yes
   F. Is the device for home use or portable? No
   G. Does the device contain drug or biological product as a component? No
   H. Is this device a kit? No
   I. Software-driven: N/A
   J. Electrically Operated: N/A
   K. Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.): No
   L. Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status: Orion Medical Products Pre-Filled 10cc Inflation Syringe with Sterile Water (K943836).

M. Submission provides comparative specifications Yes
comparative in vitro data No
performance data No
animal testing No
clinical testing No
biocompatibility testing Yes

N. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

This device type contains exactly the same material components as the predicate.

The sponsor will do endotoxin testing according to USP. A letter of declaration has been provided that states that prior to these devices being introduced commercially, all appropriate biocompatibility testing will be done to ensure that the devices pass ISO 10993.

O. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? Yes

P. RECOMMENDATION:

I believe that this device is equivalent to: 80 EZL

Classification should be based on:

876.5130 Class: II
(Accessory to a Foley Catheter)

Viola Hibbard 5/27/03
Viola Hibbard

Primary Care Solutions, Inc.

40420 Free Fall Avenue
Zephyrhills, FL, 33542
Phone: (813) 779-7226
Fax: (813) 715-4084

May 27, 2003

Ms. Viola Hibbard
Centers for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Dear Viola:

Per our discussion, I have enclosed the following:

- A declaration letter regarding biocompatibility and endotoxin testing
- Package inserts for the syringes
- A revised 510(K) Summary
- A page reflecting the Device name and Indications for use

If you like, I will send an original for your files. Please let me know.

Thank you.

Sincerely,

Ronald L. Maddix
Vice President, Marketing

Primary Care Solutions, Inc.

40420 Free Fall Avenue
Zephyrhills, FL, 33542
Phone: (813) 779-7226
Fax: (813) 715-4084

May 26, 2003

Ms. Viola Hibbard
Centers for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Reference: 510(K) Number: K030813

Dear Ms. Hibbard:

This letter will serve as Primary Care Solutions, Inc.'s declaration that it will conduct appropriate biocompatibility tests and endotoxin level testing on its 10cc and 30cc pre-filled sterile water syringes prior to these devices being introduced commercially. This testing will be done to ensure that the devices pass ISO 10993 and that endotoxin levels are within those safe levels established by USP.

Thank you.

Sincerely,

Ronald L. Maddix

Ronald L. Maddix
Vice President, Marketing & Sales

PACKAGE INSERT

10cc Pre-filled Sterile Water Syringe
for Foley Catheter Balloon Inflation

Contents Sterile Water
to inflate catheter only.
Connect syringe tip directly
to valve and engage plunger
to inflate balloon.

NOT FOR INJECTION

No antimicrobial or other substance added.
Sterility guaranteed unless container is opened or damaged.
Federal Law restricts this device to sale by or on the
order of a healthcare practitioner.

PACKAGE INSERT

30cc Pre-filled Sterile Water Syringe
for Foley Catheter Balloon Inflation

Contents Sterile Water
to inflate catheter only.
Connect syringe tip directly
to valve and engage plunger
to inflate balloon.

NOT FOR INJECTION

No antimicrobial or other substance added.
Sterility guaranteed unless container is opened or damaged.
Federal Law restricts this device to sale by or on the
order of a healthcare practitioner.

 K030813

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
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Sterilization Facility:	FOOD TECHnology Service, Inc. 502 Prairie Mine Road Mulberry, FL 33860
Classification Name:	Syringe, Balloon Inflation
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Predicate Devices:	K943836 – Pre-Filled 10cc Inflation Syringe with Sterile Water Orion Medical Products, Inc. Wheeling, IL 60090
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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.

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)

Hibbard, Viola

From: Rmatpar@aol.com
Sent: Monday, May 26, 2003 12:25 PM
To: VSH@CDRH.FDA.GOV
Subject: Re: K030813Deficiencies

Viola,

Per our conversation on Friday between you, Pat and me, I have revised the 510(K) summary as you requested and I believe it now includes all the information as required per Sec. 807.92, Content and format of a 510(K) summary. I can fax this to you or e-mail the entire 510(K) along with revised summary and corrected page numbers.

With respect to the Biocompatibility issue and endotoxin levels, I have written a declaration letter certifying that these tests will be complete and in our files prior to the syringes being released to the market.

With respect to the volume and content of the syringes, each is clearly marked with volume gradations and total volume and each is marked with content being sterile water.

With respect to our discussion regarding labeling and directions for use, I have prepared a package insert for inclusion inside the poly bag that contains the syringes which gives detailed instructions for use. Again, I can fax this to you or e-mail it whichever you prefer.

I believe the above addresses the issues that you raised and I will contact you on Tuesday morning to verify as well as get clarification as to how you want me to communicate the changes and additions to you.

Thank you.

Ron Maddix
Primary Care Solutions, Inc.

Hibbard, Viola

From: Hibbard, Viola
Sent: Wednesday, May 21, 2003 2:45 PM
To: 'Rmatpar@aol.com'
Subject: K030813Deficiencies

(b)(4)

[redacted]

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K030813

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☑ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	—	
Class III Certification and Summary. **	—	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	—	
510(k) Kit Certification ***	—	

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE **Required Elements for a Declaration of Conformity to a Recognized Standard,** which		

is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		✓
b) Sterilization and expiration dating information:		
i) sterilization process	✓	
ii) validation method of sterilization process	✓	
iii) SAL	✓	
iv) packaging		✓
v) specify pyrogen free		✓
vi) ETO residues	—	
vii) radiation dose		✓
viii) Traditional Method or Non-Traditional Method	—	
c) Software Documentation:	—	

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ✓ Yes ____ No
Reviewer: Vicki Hubbard
Concurrence by Review Branch: MAR 17 2003

Date:

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?		✓
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		✓

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Viola Hubbard

Subject: 510(k) Number K030813

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?	☐ YES	☑ NO

- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☑ Enclosed
(required for originals received 3-14-95 and after)

☑ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices N/A

☐ The indication for use form (required for originals received 1-1-96 and after)

Animal Tissue Source ☐ YES ☑ NO

CPC (N)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 76/EZL/II 876.5130

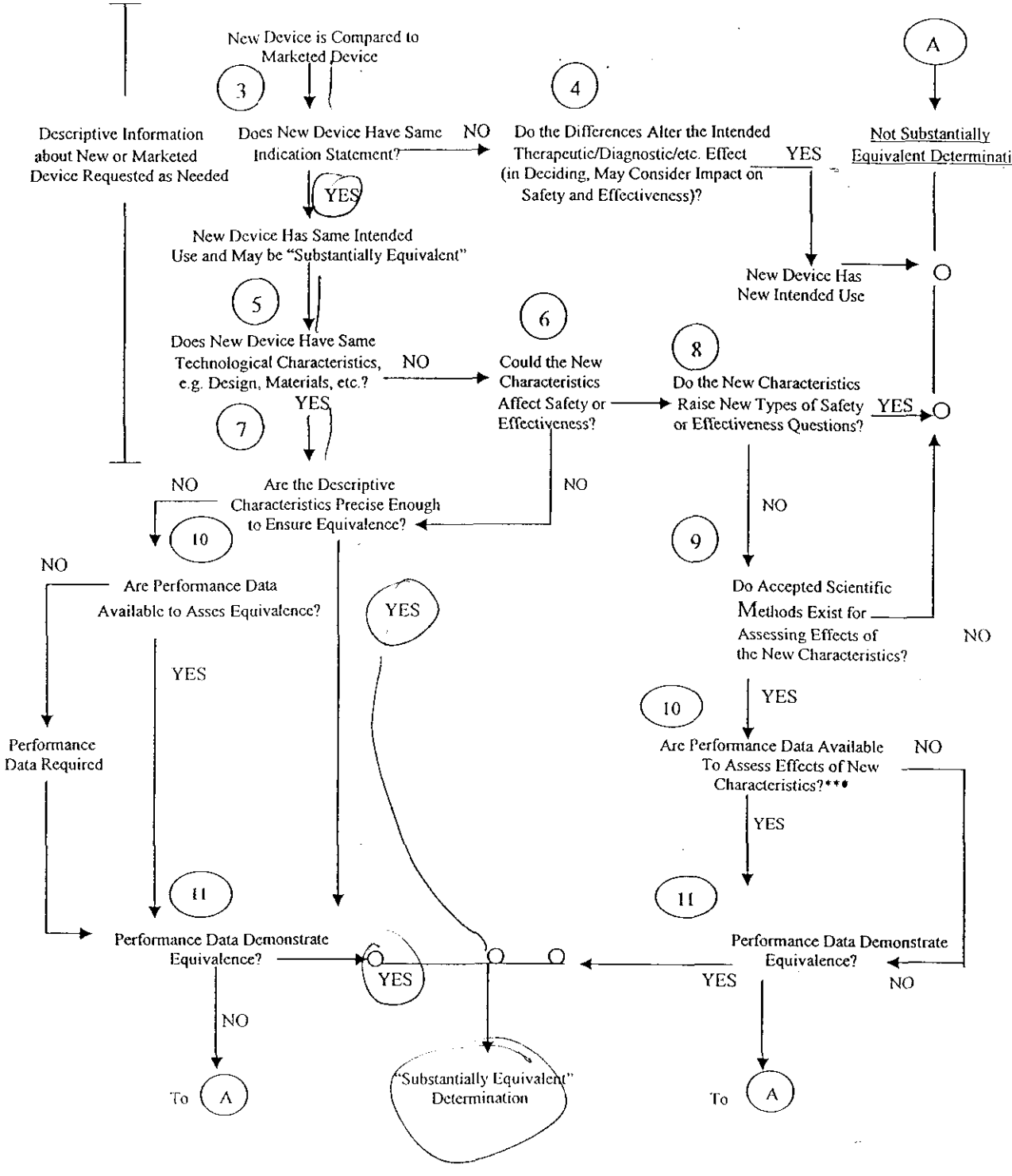
Additional Product Code(s) with panel (optional): 80/JOL/II 880.6740

Review: Patricia Cricenti (Branch Chief) — GHDB (Branch Code) — 5/30/03 (Date)

Final Review: Susan Runner (Division Director) — 5/30/03 (Date)

Revised:8/17//99

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.