K031748

AUG 2 7 2003

510(k) Summary

Submitter: VitalCare Group Inc.
8935 NW 27th Street
Miami Fl. 33172

Contact: Michael McAvenia
Director of Quality Assurance
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Name of Device:VitalCare Sterile Water and .09% Saline 10cc, 30cc pre-filled inflation syringes.

Predicate Device: Orion Life Systems- Sterile Water and 0.9% 10cc pre-filled inflation syringes.

Description of the New Device: Sterile Water and 0.9% Sodium Chloride are products that have been used in the medical community for decades, the only ingredient in the two solutions other than water is Sodium Chloride; there are no preservatives or stabilizers.
The syringes are manufactured from 100% medical grade polypropylene and contain no color or preservatives or additives.
The containers are filled with distilled water and distilled saline solution, sealed, capped and gamma irradiated for single use only.
The Sterile Water and Saline Solutions pre-filled syringes are substantially equivalent to Orion Life Systems. Sterile Water and Saline Solutions pre-filled syringes in that:

- The intended use is the same
- The performance attributes are the same

Intended Use of the New Device:

Sterile water and 0.9% Sodium Chloride pre-filled syringes are intended to be used for catheter balloon inflation. The devices are not intended to be used for wound irrigation or IV administration.

Comparison of the Technological Features of the New Device and Predicate Device:

The new device features and predicate device features are similar. The components and contents of the containers are similar.

Feature\Claim	VitalCare Group Inc. Sterile Water - 0.9% Saline Solution	Orion Life Systems Sterile Water - 0.9% Saline Solution
Contents	Sterile Water\0.9% Sodium Chloride.	Similar
Labeling	Sterile Water\Saline 10cc\30cc syringes. For Balloon Inflation. Not for injection. No antimicrobial or other substances added.	Similar
Materials	Polypropylene, Santoprene rubber	Similar

Device Common and Classification Name(s):

Common Name: Inflation Syringe.
Classification Name: Syringe, Balloon Inflation

Classification Information:

Class: Class II

Panel: General Hospital

Product Code: JOL

Cite: 880

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Michael Mcavenia
Director of Quality Assurance
VitalCare Group, Incorporation
8935 N.W. 27th Street
Miami, Florida 33172

Re: K031748
Trade/Device Name: VitalCare Sterile Water and 0.9% Saline 10cc, 30cc Pre-Filled Inflation Syringe
Regulation Number: 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZL
Dated: April 16, 2003
Received: June 13, 2003

Dear Mr. Mcavenia:

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

INDICATIONS FOR USE

510(k) Number: K031748

Device Name:	VitalCare Sterile Water and 0.9% Sodium Chloride Pre-Filled Syringes.
Indications for Use:	VitalCare Sterile Water and 0.9% Sodium Chloride. The10cc/30cc syringes are used for balloon inflation. Devices are not intended for wound irrigation, injection or IV Administration.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The Counter Use _____
(Per 21 CFR 801.109)

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

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