2/22/99

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CORPORATION

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K984441

SUMMARY OF SAFETY AND EFFECTIVENESS

December 10, 1998

Trade Name: KVO Check Valve Accessory

Common Name: Check Valve

Classification Name: Set, Administration, Intravascular

All questions and/or comments concerning this document should be made to:

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1.0 GENERAL INFORMATION

1.1 Purpose of Submission

1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation intends to market an accessory component for the I-Flow One•Step KVO infusion pump (K932740).

1.1.2 Trade Name: KVO Check Valve Accessory

1.1.3 Common Name: Check Valve

1.1.4 Classification Name: Set, Administration, Intravascular

1.1.5 Classification Panel: General Hospital and Personal Use Device

1.2 Statement of Equivalence

1.2.1 The KVO Check Valve Accessory, hereafter referred to as the KVO Accessory, is simply the Supravalve Check Valve Assembly manufactured by Vernay Laboratories, Inc.

1.2.2 The KVO Accessory is substantially equivalent to the B. Braun Low Pressure Check Valve and Medex, Inc. Check Valve.

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

2.1 Description of the KVO Accessory

2.1.1 The KVO Accessory is simply the Supravalve Check Valve Assembly manufactured by Vernay Laboratories, Inc.

2.1.1.1 Vernay has over 50 years of experience designing and manufacturing check valves.

2.1.1.2 The Supravalve Check Valve Assembly manufactured by Vernay is sold as a component to medical device manufacturers.

2.1.1.3 I-Flow Corporation intends to sterilize, package and label the Supravalve as the KVO Accessory for use with the I-Flow One•Step KVO infusion pump.

2.1.2 The KVO Accessory housing consists of polycarbonate with a standard female luer lock connector on the inlet port and male luer connector with a locking rotating collar on the outlet port.

2.1.2.1 The rotating collar facilitates easy assembly and a secure connection to the Y-site of the One•Step KVO.

2.1.2.2 The female connector may attach to a needleless connector followed by a secondary medication line.

2.1.3 The check valve consists of a one-piece, elastomeric duckbill which allows free flow with positive differential pressure. With negative differential pressure, backflow is checked.

2.1.3.1 The check valve has a low cracking pressure to allow use of standard IV gravity drug bags as a secondary medication line.

2.2 **Product Configuration**

2.2.1 The following KVO Accessory model will be available:

2.2.1.1 EV-0001: KVO Check Valve Accessory.

2.2.1.1.1 The check valve is manufactured by Vernay Laboratories, model # 1300-233.

2.3 **Power Requirements**

2.3.1 The KVO Accessory does not require any external power.

3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1 **Standard Operating Conditions:**

Priming/Residual Volume:	<= 0.5 ml
Test Solution:	0.9% NaCl
Cracking Pressure:	>= 0.1 psi
Backpressure Withstand:	<= 10 psi

3.2 **Back Testing:** Two tests were performed, both a high and low pressure, to determine backflow effects on the check valve. The first test air pressurized 20 samples of the check valve with a 10 psi backflow pressure. No leaks were observed. The second test was performed on 30 samples of the check valve with 8 inches H_2O backflow for 4 hours. There were no backflow incidents observed.

3.2.1 The check valve performed within specification during both high and low backpressure tests.

3.3 **Safety / Alarm Functions**

3.3.1 The KVO Accessory will not be recommended for any application that exceeds the maximum internal pressure of the system.

3.3.2 If for any reason the patient needs to stop his or her infusions, each One•Step KVO infusion pump is supplied with a pinch clamp to stop the infusion.

3.3.3 This device contains no alarms or indicators for flow other than visual.

4.0 BIOLOGICAL SPECIFICATIONS

4.1 Biological testing is in conformance with ISO 10993 Part 1 for all fluid path components of the KVO Accessory.

5.0 CHEMICAL AND DRUG SPECIFICATIONS

5.1 Compatibility and Stability

5.1.1 There are no specific drugs referenced in the labeling for the KVO Accessory.

6.0 INTENDED USE

6.1 The KVO Accessory is intended to allow fluid flow in one direction and stop, or check, fluid flow in the opposite direction.

6.2 The KVO Accessory is intended to be used with the I-Flow One•Step KVO infusion pump.

6.3 The KVO Accessory is single patient use only.

6.4 No testing has been conducted to determine the efficacy of the KVO Accessory for the delivery of blood, blood products, lipids or fat emulsions. The KVO Accessory is not intended for the delivery of blood, blood products, lipids or fat emulsions.

7.0 LABELS AND LABELING

7.1 I-Flow Corporation believes the proposed labels and labeling, where appropriate, meets the requirements of 21 CFR Part 801 as it relates to a determination of intended use and adequate directions for use.

7.2 The KVO Accessory Directions for Use labeling:

7.2.1 Provides comprehensive directions for preparation and use for the KVO Accessory.

7.2.2 Describes the intended use.

7.2.3 Contains caution information.

7.2.4 Contains the prescription statement required under 801.109 (b)(1).

7.2.5 Includes the specifications of the KVO Accessory.

7.3 Identification labels and labeling

7.3.1 I-Flow has developed product identification labeling for the KVO Accessory.

7.4 Packaging labels

7.4.1 Contains the prescription statement required under 801.109(b)(1).

8.0 STANDARDS

8.1 There are currently no standards established for check valves.

9.0 PACKAGING

9.1 The KVO Accessory will be purchased in bulk, non-sterile and packaged by I-Flow.

9.2 Each KVO Accessory will be packaged separately in a Tyvek or Form/Fill/Seal pouch.

9.3 Packaging is suitable for either radiation or ETO sterilization.

9.4 Package aging tests have been conducted on the Tyvek pouch packaging material. The results of bacterial dust challenge testing has determined that the pouches used to package the disposable KVO Accessory maintain sterility in excess of three years.

10.0 STERILIZATION INFORMATION

The KVO Accessory shall be sterilized as follows:

10.1 The methods of sterilization are gamma radiation (Cobalt 60) or ETO gas.

10.2 Sterilization validation methodology is by ANSI/AAMI ST32-1991 / EN552 Method 1 for gamma radiation.

10.2.1 The gamma radiation dose validated for this product is 25 to 35 KGy (2.5 to 3.5 Mrad).

10.3 Sterilization validation methodology is by ANSI/AAMI/ISO 11135-1994 / EN550 for ETO gas sterilization.

10.3.1 For ETO sterilized product, the maximum levels of gas residuals for ethylene oxide, ethylene chlorohydrin and ethylene glycol are consistent with the FDA proposed rule, 43 FR 27482 (June 23, 1978).

10.3.2 The maximum residual limits are 25 ppm for ethylene oxide, 25 ppm for ethylene chlorohydrin, and 250 ppm for ethylene glycol.

10.4 The sterile product under review here will have a sterilization assurance level (SAL) of 10^{-6}. Sterility testing is by spore strip for ETO. Under AAMI Method 1 for Gamma sterilized product, no sterility test is required.

10.5 The product is labeled pyrogen free and is tested for pyrogens using either the USP Rabbit Pyrogen Test or LAL test methods.

10.5.1 I-Flow products have been validated for LAL testing.

10.5.2 Either method may be used as necessary.

11.0 COMPARISON TO LEGALLY MARKETED DEVICES

See Table 1 that follows this section for more specific information.

11.1 Intended Use

11.1.1 The KVO Accessory, B. Braun Low Pressure Check Valve and Medex Check Valve are intended:

11.1.1.1 To allow fluid flow in one direction and stop, or check, fluid flow in the opposite direction.

11.1.1.2 The KVO Accessory is intended to be used with the I-Flow One•Step KVO infusion pump.

11.2 Device Descriptions

11.2.1 The KVO Accessory

11.2.1.1 The KVO Accessory is simply the Supravalve Check Valve Assembly manufactured by Vernay Laboratories, Inc.

11.2.1.1.1 Vernay has over 50 years of experience designing and manufacturing check valves.

11.2.1.1.2 The Supravalve Check Valve Assembly manufactured by Vernay is sold as a component to medical device manufacturers.

11.2.1.1.3 I-Flow Corporation intends to packaged, label and sterilize the Supravalve as the KVO Accessory for use with the I-Flow One•Step KVO infusion pump.

11.2.1.2 The KVO Accessory housing consists of polycarbonate with a standard female luer lock connector on the inlet port and male luer connector with a locking rotating collar on the outlet port.

11.2.1.2.1 The rotating collar facilitates easy assembly and a secure connection to the Y-site of the One•Step KVO device.

11.2.1.2.2 The female connector may attach to a needleless connector followed by a secondary medication line.

11.2.1.3 The check valve consists of a one-piece, elastomeric duckbill which allows free flow with positive differential pressure. With negative differential pressure, backflow is checked.

11.2.1.3.1 The check valve has a low cracking pressure to allow use of standard IV gravity drug bags as a secondary medication line.

11.2.2 The B. Braun Low Pressure Check Valve (model # S5401068)

11.2.2.1 The B. Braun Check Valve is very similar to the KVO Accessory.

11.2.2.2 Both the B. Braun Check Valve and the KVO Accessory consist of polycarbonate housing with a standard female luer lock connector on the inlet port and male luer connector with a locking rotating collar on the outlet port.

11.2.2.3 Both contain elastomeric check valves which allow free flow with positive differential pressure and prevent backflow with negative differential pressure.

11.2.2.3.1 Both check valves have a low cracking pressure.

11.2.2.3.2 The B. Braun check valve consists of a diaphragm (disk) as opposed to a duckbill as in the KVO Accessory.

11.2.3 The Medex, Inc. Check Valve (model # B1741-05)

11.2.3.1 The Medex Check Valve is very similar to the KVO Accessory.

11.2.3.2 Both the Medex Check Valve and the KVO Accessory consist of plastic housing with a standard female luer lock connector on the inlet port and male luer connector on the outlet port. The Medex Check Valve does not have a rotating collar on the outlet port.

11.2.3.3 Both contain elastomeric check valves which allow free flow with positive differential pressure and prevent backflow with negative differential pressure.

11.2.3.3.1 Both check valves have a low cracking pressure.

11.2.3.3.2 Both check valves have a one-piece duckbill design made of silicone.

11.2.4 Materials

11.2.4.1 The KVO Accessory and its predicate devices have similar materials. All fluid path materials of the KVO Accessory are in conformance with ISO 10993 Part 1.

11.3 Based upon the data presented in this section 11.0 and Table 1, I-Flow Corporation has determined that the KVO Accessory is substantially equivalent to the named predicate devices.

Table 1
Comparison to Legally Marketed Devices

Comparison Element	KVO Accessory (subject device)	SE[1] B. Braun Low Pressure Check Valve	SE[1] Medex Medical Check Valve
Intended Use	To allow fluid flow in one direction and stop, or check, fluid flow in the opposite direction. The KVO Accessory is intended to be used with the I-Flow One•Step KVO infusion pump.	To allow fluid flow in one direction and stop, or check, fluid flow in the opposite direction.	To allow fluid flow in one direction and stop, or check, fluid flow in the opposite direction.
Reuse Capability	Disposable, single patient use	Disposable, single patient use	Disposable, single patient use
Description	Female luer lock inlet port, male luer lock with rotating collar outlet port, duckbill check valve.	Female luer lock inlet port, male luer lock with rotating collar outlet port, diaphragm check valve.	Female luer lock inlet port, male luer lock outlet port, duckbill check valve.
Power Requirements	None	None	None
Check Valve Mechanism	Elastomeric duckbill	Elastomeric diaphragm (disk)	Elastomeric duckbill
Fluid Path Components			
Housing	Polycarbonate	Polycarbonate	Co-polyester
Check Valve	Silicone	Silicone	Silicone
Luer Caps	ABS, Polycarbonate or High Density Polyethylene		
Packaging (sterile)	Tyvek Pouch or Form/Fill/Seal	Tyvek Pouch or Form/Fill/Seal	Tyvek Pouch or Form/Fill/Seal
Sterilization	Gamma or ETO	Gamma or ETO	Gamma or ETO
Product Code	80 FPA	80 FPA	80 FPA

[1]SE = Substantially Equivalent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 22 1999

Shane P. Noehre, R.A.C.
Regulatory Affairs Specialist
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Re: K984441
Trade Name: KVO Check Valve Accessory, Model EV-0001
Regulatory Class: II
Product Code: FPA
Dated: December 10, 1998
Received: December 14, 1998

Dear Mr. Noehre:

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 (Premarket 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 premarket 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.

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

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510(k) Number (if known): K984441

Device Name: KVO Check Valve Accessory

Indications for Use:

The KVO Accessory is intended to allow fluid flow in one direction and stop, or check, fluid flow in the opposite direction. The KVO Accessory is intended to be used with the I-Flow One•Step KVO infusion pump.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984441

(Optional Format 1-2-96)