

Shepherd Laboratories, Inc.

402 Coast Boulevard South
La Jolla, CA 92037

SEP - 8 1997

May 1, 1997

Document Mail Center (HFZ-401)
Center of Devices and Radiological Health
Food & Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850, USA

RE: Summary of Safety and Effectiveness Information for Shepherd Laboratories®, Dye Stop and Save - Quick Fill®, Contrast Administration Set

Attention: Document Control Clerk

This summary of safety and effectiveness information for the Shepherd Laboratories, Inc., Dye Stop and Save-Quick Fill® Contrast Administration Set is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Intended Use

The Shepherd Laboratories, Inc., Dye Stop and Save-Quick Fill® Contrast Administration Set is intended to administer contrast agent to a patient while isolating the patient's bodily fluids from the contrast bottle to allow reuse of the contrast bottle on subsequent patients, and to exclude air from entering the tubing connecting the contrast bottle to the control syringe.

Summary of Characteristics

Contrast Agent Administration Sets are regularly used with anesthesia manifolds to administer contrast agents to patients. A number of manufacturers market sets for this purpose. They are much like standard IV administration sets that have volume measuring burettes installed. Most of these contrast administration sets are intended for use on only one patient to prevent bacteriological cross contamination. As a result, some contrast agent, which is a relatively expensive material, is potentially wasted in an effort to prevent such bacteriological cross contamination.

Contrast agent administration sets have been marketed which use check valves in the contrast agent flow line to prevent backflow of the agent from a patient to the supply bottle. In addition, administration sets are marketed which include a "quick fill" feature that eliminates the need to wait a period of time to allow the burette to fill. The "quick fill" feature allows the user to create a higher pressure in the contrast agent bottle than in the burette chamber. This differential pressure causes the contrast agent to flow into the burette agent rapidly.

The Dye Stop and Save-Quick Fill®, Contrast Agent Administration Set consists of two major components which perform the task of administering the contrast agent. The first is a Spike Assembly that is used to communicate the contrast agent out of the contrast agent bottle. The second is a Deformable Chamber and Tubing Set which blocks the contrast agent from retrograde flow, provides flow initiation means via the deformable chamber, displays volume flow indications in the chamber, and provides a chamber outlet float valve which prevents air from entering the tubing line to the patient.

The Dye Stop and Save-Quick Fill® device, therefore, is designed to administer contrast agents to a patient like other such devices but also:

1. Isolates a patient's bodily fluids from a contrast agent bottle to allow the use of the remaining contrast agent in the bottle on subsequent patients.
2. Provides a simple means of initiation of rapid fill flow.
3. Excludes air from entering the tubing connecting the contrast agent chamber with the control syringe.

The Dye Stop and Save-Quick Fill® device incorporates a vented spike that is used to penetrate the stopper of the contrast agent bottle. A disconnect point is included just downstream of the spike. This disconnect point is provided with an automatic shut off valve which prevents contrast from leaking out of the disconnect when it is separated. A sterility protection cap is provided to close the end of the disconnect to prevent contamination.

Downstream of the disconnect point are two one-way valves. These two valves are mounted in series and provide added security. These valves prevent a patients' bodily fluids from traveling backwards and entering the contrast agent bottle.

Downstream of the two one-way valves is a deformable burette chamber. At the top of the burette chamber is a high-pressure check valve. When the burette chamber is squeezed, the high-pressure check valve will open allowing air within the burette chamber to vent to the atmosphere. When the squeezed burette chamber is released a partial vacuum is created within the burette chamber.

This partial vacuum causes the aforementioned differential pressure to occur, drawing contrast agent from the bottle into the burette chamber in a quick fill mode.

Contained in the bottom of the burette chamber is a floating check valve that acts to prevent air from escaping from the bottom of the burette chamber when fluid flow ceases and the burette empties. A section of tubing then connects the burette chamber to a manifold/control syringe assembly.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Paul Teirstein".

Paul S. Teirstein, M.D.
President
Shepherd Laboratories, Inc.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Paul S. Teirstein, M.D.
President
Shepherd Laboratories, Incorporated
402 Coaste Boulevard South
LaJolla, California 92037

SEP - 8 1997

Re: K971624
Trade Name: Dye Stop and Save - Quickfill Administration
Set
Regulatory Class: II
Product Code: FPA
Dated: July 7, 1997
Received: July 9, 1997

Dear Dr. Teirstein:

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.

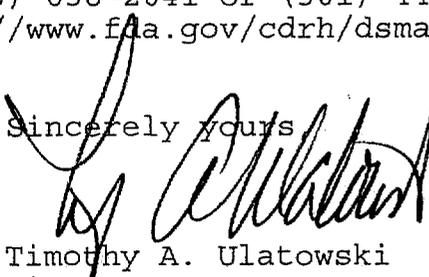
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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

K971624

Re: 510(k) K971624

Rev. September 3, 1997

Shepherd Laboratories, Inc.

**Dye Stop and Save - Quick Fill®,
Contrast Agent Administration Set**

Statement of Indication for Use

The Dye Stop and Save-Quick Fill® device is indicated as a means to administer contrast agents to a patient and to isolate a patient's bodily fluids from the contrast agent bottle to allow the use of the remaining contrast agent in the bottle on subsequent patients. It is also indicated to provide a simple means of initiation of rapid fill flow, and to exclude air from entering the tubing connecting the contrast agent chamber with a control syringe.

Patricia Caserite

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

510(k) Number

K971624