

AUG 11 1998

K982465

DeRoyal Industries, Inc.

DeFogger

510(k) Summary

Summary of the Safety and Effectiveness Information Upon Which an Equivalence Determination Could Be Based

SUBMITTER INFORMATION

NAME: DeRoyal Industries, Inc. TELEPHONE: (423) 938-7828
ADDRESS: 200 DeBusk Lane CONTACT: Lois Marsh
Powell, TN 37849 DATE OF PREPARATION: July 14, 1998

DEVICE NAMES

NAME: DeRoyal Industries, Inc. DeFogger
COMMON/USUAL NAME: Endoscope Fog Reduction Device
CLASSIFICATION NAME (if known): Endoscope and/or Accessories

PREDICATE OR LEGALLY MARKETED DEVICES

Struckmeyer, O.R. Concepts, Inman Medical Corporation, Dexide, and Eagle Medical International.

DEVICE DESCRIPTION

The DeRoyal Industries, Inc. DeFogger functions in the same manner as predicate devices in that it is intended to be used during endoscopic, laparoscopic, gastroscopic, and arthroscopic procedures, as well as any other procedures which require the use of an endoscope device to prevent fogging of the endoscope lens.

Device Design/ Materials Used/Physical Properties: The DeRoyal Industries, Inc. DeFogger is made of materials commonly used for this purpose. The primary material components are a solution consisting of Monawet MO-70E, Isopropyl Alcohol, and Water. The solution is applied with an Adhesive-Backed X-Ray Detectable Polyurethane Foam Pad.

DEVICE INTENDED USE

The DeRoyal Industries, Inc. DeFogger is indicated for use during endoscopic, laparoscopic, gastroscopic, and arthroscopic procedures to prevent fogging of the endoscope lens.

TECHNOLOGICAL COMPARISON WITH PREDICATE DEVICES

Characteristics and Materials	DeRoyal	Predicate Devices
Solution	Surfactant in Water and Isopropyl Alcohol.	Same or Similar Material
Solution Container	6 gram Plastic, Squeeze Bottle	Same
Sponge	Adhesive-Backed, X-Ray Detectable Foam Pad	Same or Similar Material
Disposable	Yes	Yes
Sterility	Sterile	Yes



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 1998

Ms. Lois Marsh
Regulatory Affairs
DeRoyal Industries, Inc.
200 DeBusk Lane
Powell, TN 37849

Re: K982465
DeRoyal Industries, Inc. DeFogger
Dated: July 14, 1998
Received: July 15, 1998
Regulatory Class: II
21 CFR 876.1500/Procode: 78 KOG

Dear Ms. Marsh:

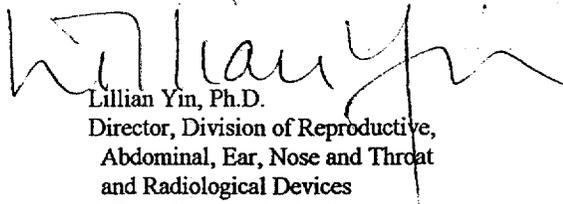
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirements, 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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K982465

Device Name: DeRoyal Industries, Inc. DeFogger

Indications for Use:

The DeRoyal Industries, Inc. DeFogger is indicated for use during endoscopic, laparoscopic, gastroscopic, and arthroscopic procedures, as well as any other procedures which require the use of an endoscope device, to prevent fogging of the endoscope lens.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin M. Gallard for BRB/Lly

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K982465

Prescription Use
(Per 21 CFR §801.109)

OR

Over-The-Counter Use