

**510(k) SUMMARY  
As Required by 807.92(c)**

9/11/1998

1. **Submitter:** DHD Healthcare  
125 Rasbach Street  
Canastota, NY 13032

Phone: 315-697-2221  
Fax: 315-697-8083

**Contact:** Jean Wallace, Manager, Regulatory Affairs

2. **Device Name**

- Trade Name - Lichen (Final Name to be determined)
- Common name - Bacterial In-Line Breathing Filter with Tubing (Ambient Air)
- Classification name - Filter, Bacterial, Breathing-Circuit

3. **Predicate Device:** Pulmoguard™ Bacterial and Virus Filter (K934509)  
SDI Diagnostics  
10 Hampden Drive, Easton, MA 02375

4. **Device Description**

The DHD Lichen Product is a kit consisting of a hydrophobic bi-directional filter with tubing that is connected to each side of the hydrophobic bi-directional filter. This assembled filter kit is a single-patient-use device intended for infection control for use with low flow pressure indicators and both inspiratory and expiratory maneuvers with low flow pressure indicators and gauges where the patient exhales at a pressure of less than 120cm H<sub>2</sub>O.

5. **Intended Use**

The DHD Healthcare Lichen Filter Kit is intended to filter airborne particulate matter and certain bacteria (i.e., Staphylococcus) with a mean diameter of 3.2 microns or greater. The Lichen may reduce cross-contamination between patient and equipment attachments such as use with Respiratory Therapy low flow pressure indicators and gauges (i.e., an example would be for use with the DHD TheraPEP® Pressure Indicator and aneroid gauges). The use of the Lichen Filter Kit may allow the re-use of aneroid gauges and pressure indicators from patient to patient per your institution's protocol. The device also incorporates tubing for use in connection to low flow pressure indicators and gauges.

6. **Technological Information**

The filter bodies of both the Pulmoguard and Lichen are both made of rigid plastic. The Pulmoguard's filter body is made from Polycarbonate Resin. Lichen's filter body is a modified acrylic. The filter media's of both the Pulmoguard and Lichen are made of a polyester nonwoven fabric coated with an acrylic syrup. Lichen has flexible tubing made of Kraton G2705 Thermoplastic Elastomer. Pulmoguard has no flexible tubing. All materials used with Lichen meet USP Class VI and exceed biocompatibility requirements.

Both the Pulmoguard and Lichen claim to reduce the risk of cross-contamination between patients and between patients and healthcare providers. Pulmoguard claims to be a bacterial/viral filter and to stop transmission of 99.8% of bacteria and viruses. Lichen claims to be a bacterial filter with a minimum Bacterial Filtration Efficiency of 99.97%.

7. **Summary of Studies**

There were no specific studies completed in association with this submission.

8. **Conclusions Drawn from Studies**

None



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 14 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

Ms. Jean Wallace  
DHD Healthcare  
One Madison Street  
Wampsville, NY 13163

Re: K980662  
Lichen Bacterial In Line Breathing Filter  
Regulatory Class: II (two)  
Product Code: 73 CAH  
Dated: June 15, 1998  
Received: June 17, 1998

Dear Ms. Wallace:

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 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). 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.

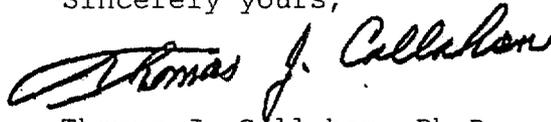
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Jean Wallace

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) 594-4648. 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,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Lichen 510(k) Submission  
Intended Use Statement**

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510(k) Number (if known): K980662

Device Name: Lichen Filter Kit

Indications For Use:

**1 - Purpose/Claims:**

The DHD Healthcare Lichen Filter Kit is intended to filter airborne particulate matter and certain bacteria (i.e., Staphylococcus) with a mean diameter of 3.2 microns or greater. The Lichen may reduce cross-contamination between patient and equipment attachments such as use with Respiratory Therapy low flow pressure indicators and gauges (i.e., an example would be for use with the DHD TheraPEP® Pressure Indicator and aneroid gauges). The use of the Lichen Filter Kit may allow the re-use of aneroid gauges and pressure indicators from patient to patient per your institution's protocol. The device also incorporates tubing for use in connection to low flow pressure indicators and gauges.

**Caution Statement:** Follow the recommended cleaning frequency and infection control procedures included in the gauge or pressure indicator's original labeling when used with the Lichen filter. Do not alter your institution's standard infection control procedures for equipment reuse.

**2 - Target Patient Population:**

Patients requiring the use of low flow pressure indicators and gauges in respiratory therapy as determined by professional medical personnel. The DHD Lichen Filter is recommended for use with the DHD TheraPEP® Pressure Indicator and aneroid gauges.

**3 - Intended Environment For Use**

- 4.1 Labeling reflects the statement: "Federal (USA) Law restricts this device to sale by or on the order of a physician."
- 4.2 Hospital or home after a period of training.

**4 - Legally Marketed Predicate Devices:**

Manufacturer: SDI Diagnostics, Inc. 510(k) No. K934509  
Shovel Shop Square  
Building 11  
North Easton, MA 02356

The SDI Diagnostics, Inc., Pulmoguard, is distributed by: Queset Medical  
Brockton, MA 02403  
Phone: 1-800-728-8230

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

*Lark W. Woodroffe*  
9-11-98

(Optional Format 1-2-96)