

K973314



NOV 21 1997

Non-Confidential Summary of Safety and Effectiveness  
September 1, 1997

Micro Direct, Inc.  
1485 Lisbon Street  
Lewiston, ME 04240

Tel - (207) 786-7808

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**Official contact:** David R. Staszak, President

**Proprietary or Trade Name:** SpiroSafe Filter

**Common/Usual Name:** Disposable bacterial/viral filter

**Classification Name:** 73 CAH - Filter, bacterial

**Intended device:** Disposable bacterial/viral filter

**Predicate devices:** PDSI KoKo Filter - K914272

**Device description:** A disposable bacterial/viral filter used in pulmonary function testing

**Indicated use:**

The intended device filters possible bacteria and viruses from the patient exhalation when performing pulmonary function testing.

**Targeted population:**

Patients requiring lung function evaluations.

**Environment of use:**

Places where a qualified clinician desires to take lung function measurements .

**Comparison to predicate devices:**

Attribute	Intended device	PDSI KoKo Filter
<b>Use</b>		
Intended as a bacterial/viral filter	Yes	Yes
Intended for use during pulmonary function test	Yes	Yes
<b>Design</b>		
Single patient use	Yes	Yes

**Comparison to predicate devices (continued):**

<b>Attribute</b>	<b>Intended device</b>	<b>PDSI KoKo Filter</b>
<b>Materials</b>		
Housing - Impact Polystyrene	Yes	Yes
Filter Media	Electrostat	Filtrete
<b>Performance</b>		
Bacterial Efficiency	>99%	99.99%
Viral Efficiency	>99%	99.98%
Resistance to Airflow (cmH <sub>2</sub> O/L/Sec. @ 12/L/Sec.)	>1.5	.9

**Differences**

The only difference is that the intended filter uses Electrostat filter media manufactured by Enhanced Filter Company of Ventura, CA and the PDSI KoKo filter uses Filtrete manufactured by 3M. Both are synthetic electret filter media.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 21 1997

Mr. David R. Staszak  
Micro Direct, Inc.  
1485 Lisbon Street  
St. Lewiston, Maine 04240

Re: K973314  
SpiroSafe Filter  
Regulatory Class: II (two)  
Product Code: 73 CAH  
Dated: September 1, 1997  
Received: September 3, 1997

Dear Mr. Staszak:

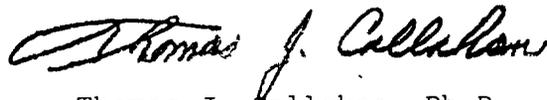
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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) 594-4648. 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/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

**Indications for Use Statement**

**510(k) Number**   K973314   (To be assigned)

**Device Name:** SpiroSafe Filter

**Indications for Use:** To filter possible bacteria and viruses from the patient exhalation when performing pulmonary function testing

**Targeted population:** Patients requiring lung function measurements

**Environment of use:** Places where a qualified clinician desires to take these lung measurements

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Art A. Carloush*  
\_\_\_\_\_  
Division Sign-Off  
of **Cardiovascular, Respiratory,**  
**Biological Devices**   K973314    
Number \_\_\_\_\_

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use