

APR - 2 2004

K031982

Birdsong Medical LeverHaler Spacer 510(k) Summary:

In accordance with 21 CFR section 807.92 BirdSong Medical is submitting the following safety and effectiveness summary.

1) Submitter Information

Eric Fugelsang
President
BirdSong Medical Devices, Inc.
1456 Rt. 22, Suite A103
Brewster, NY 10509

2) Name of Device

Proprietary Name: LeverHaler Spacer
Common Name is Handheld Spacer
Classification Name: Nebulizer Accessory

3) Substantially equivalent to: OptiHaler (Healthscan Products, Inc.), K911807.

4) Device Description and System Overview:

The LeverHaler Spacer (Spacer) is an injection molded polycarbonate spacer device intended for use with FDA approved metered dose inhalers (MDI's). The MDI canister fits through a slot in a lever located on the top of the spacer. Activation of the MDI canister can be done by manually pressing down on the MDI (typical activation), or the MDI may be actuated by depressing the Lever Actuator down towards the top of the spacer body.

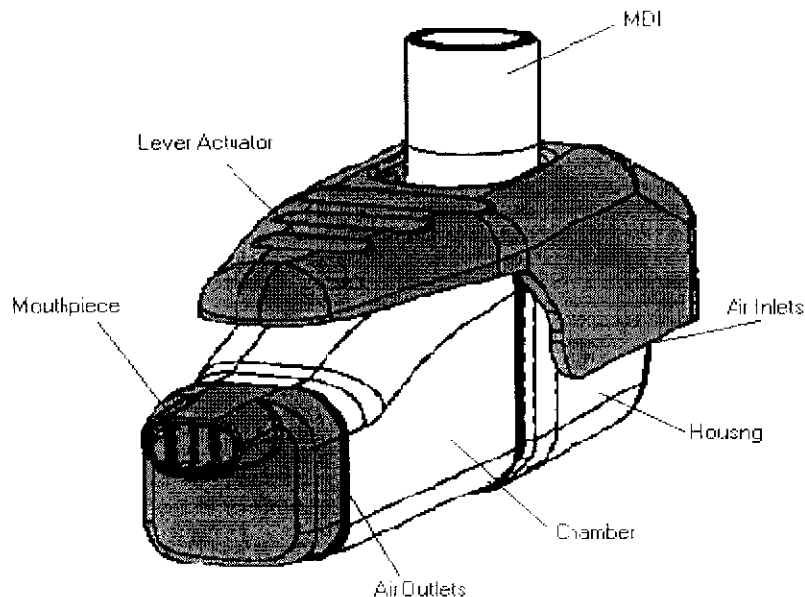


Figure 1: Diagram of LeverHaler Spacer

The device is made from polycarbonate injection molded plastic and is designed to disassemble and snap back in place for cleaning. When not in use, up to two MDI canisters can be stored inside of the LeverHaler Chamber.

The product is sold non-sterile, and is a single-patient device intended to be used for up to one year. Labeling reflects proper cleaning and use of the device. All materials used in the manufacturing of this device are identical to a defined predicate device.

This device does not generate aerosols. Its purpose is to provide an effective mixing chamber for the aerosols produced by a metered dose inhaler to assure better aerosol distribution and concentration for inhalation by the patient. This is a prescription device.

The device has no detection capabilities. It is mechanical and has no alarm functions or capabilities. There is no software integrated or used in conjunction with this device.

Product testing has been completed according to the "Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators (10-01-93)." Product testing performed by Birdsong Medical provides clear proof that the LeverHaler Spacer is superior to the MDI and is comparable or superior to the predicate devices tested. The premarket notification submitted to FDA contains a full discussion of product testing, which includes delivered aerosol potency, MMAD, GSD, particle distribution, retained aerosols (Plume Analysis) and life testing. All tests included comparative testing of the two predicate devices and the LeverHaler Spacer.

Design Considerations and Operation of the Device:

The device is intended to be used with FDA approved MDI drugs for treatment of lung disease. The Lever Actuator is designed for patients with limited hand strength, coordination or dexterity. The MDI can be actuated easily with the Lever or may be actuated by depressing the MDI downwards (typical MDI activation).

Testing:

All product and comparative in vitro testing performed was based upon the requirements of the "Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators: Reviewer Guidance 10-01-93." Testing was conducted by an independent medical device manufacturer and test laboratory contracted by Birdsong Medical. All tests were performed according to documented test protocol.

The following tests were completed for the LeverHaler Spacer, and the predicate devices: OptiHaler and AeroChamber (specified in this premarket notification):

- Particle size distribution (using 3 drugs)
- Dose output testing (drug quantity and total mass using 3 drugs)
- Mean median aerodynamic diameter (MMAD)
- Geometric standard deviation (GSD)

- Plume Analysis Testing
- Single patient use testing (life testing)

No clinical testing was performed on this product.

Software Validation: Not applicable: there is no software in this product.

Sterilization Validation: Not applicable: this product is sold and used as a non-sterile product.

Biocompatibility: All materials used in this device are incorporated in other predicate devices, as well as nebulizers, connectors and mouthpieces currently sold in the marketplace, and are therefore appropriate for the intended use described herein.

Comparative Product Matrix

Table 2: 510(k) Summary - Substantial Equivalence to Predicate Devices

item:	Characteristic:	Birdsong Medical	Healthscan Products, Inc.	Monaghan Medical
	Model:	LeverHaler Spacer	OptiHaler	AeroChamber
4.	Spacer Material	Clear Polycarbonate	Clear Polycarbonate	Clear Polyester
5.	Mouthpiece and Valve	Silicone	Polycarbonate	Polyethelene and Silicone
5.	Single Patient Use?	Yes	Yes	Yes
6.	Sterility?	Non-Sterile	Non-Sterile	Non-Sterile
7.	Ventilator Use?	No	No	Yes
8.	Maximum Length of Use:	Single patient up to 365 days	Single patient Not stipulated	Single patient Not stipulated
8.	Effective Size of mixing area:	Approximately 170 ml	Approximately 90 ml	Approximately 140 ml
9.	Method of Operation:	Mechanical	Mechanical	Mechanical
10.	Prescription Device?	Yes	Yes	Yes
11.	Provided as Kit?	No	No	No
12.	Port Protection?	Yes	Yes	Yes
	Premarket Submission:	Pending	(K911807)	(K930574) (K884803)

Conclusions of all Testing: The Birdsong Medical Spacer met all design requirements and passed all validation and comparative product testing. The device is manufactured from the identical materials used in a predicate device noted in the 510(k) submission. LeverHaler performance in all in vitro tests was equivalent or superior to the comparative predicate device noted in the table above.

Based upon these results, it is our conclusion that the LeverHaler Spacer is as safe, as effective and performs as well as or better than the legally marketed predicate OptiHaler Spacer device used in comparative product testing.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2004

Mr. Eric Fugelsang
President
Birdsong Medical Devices, Incorporated
1456 Rt. 22, Suite A103
Brewster, NY 10509

Re: K031982
Trade/Device Name: Leverhaler Spacer
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: February 13, 2004
Received: February 13, 2004

Dear Mr. Fugelsang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

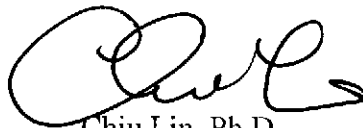
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE

[510(k)] Number: K031982

Device Name: Birdsong Medical Devices LeverHaler Spacer

Indications For Use:

The LeverHaler Spacer is a spacer device that is designed to effectively deliver respirable medical aerosols produced by most MDI's to a patient during inhalation. This product is intended for use in the treatment of lung disease. The device has been designed for use by all patients who have been prescribed MDI treatment by their physician. It is intended for use in both the hospital and homecare environments.

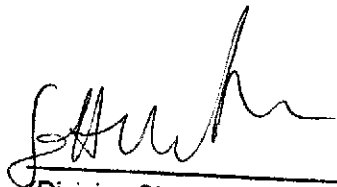
Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number: K031982