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**Spiration, Inc. Receives First FDA Approval for Bronchial Valve**

*Humanitarian Device Exemption Allows IBV® Valve System As Minimally Invasive Treatment Alternative for Patients with Prolonged Post-Operative Air Leaks*

**Redmond, Wash.** – October 24, 2008 – Spiration, Inc., a developer of novel medical devices designed to benefit patients with acute and chronic conditions of the lung, announced today that the company has received Humanitarian Device Exemption (HDE) approval from the U.S. Food and Drug Administration (FDA) for the use of its minimally invasive IBV® Valve System to control prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged, following lobectomy, segmentectomy, or lung volume reduction surgery. This FDA approval represents the first for a bronchial valve implant for the lungs.

“This FDA approval, the first for a lung device in recent memory and the first ever for a bronchial valve, is an exciting milestone and marks an advancement toward broader FDA approval of devices to treat various types of lung conditions,” said Rick Shea, president and CEO, Spiration®. “As one of only three HDE approvals so far in 2008, this approval is a significant accomplishment for Spiration.”

“Although rarely life threatening, prolonged post-operative air leaks can be a significant and costly complication of lung surgery,” said Daniel Sterman, M.D., director of Interventional Pulmonology at the University of Pennsylvania Medical Center in Philadelphia. “The HDE approval of the IBV Valve System will have a positive impact on the lives of patients who are having difficulty recovering from lung surgery. We are pleased that this approval provides a new treatment alternative for these patients.”

Conventional treatments for prolonged air leaks include further surgical intervention, the insertion of drain tubes into the chest, or lung tissue sealing (pleurodesis). These approaches can result in additional complications, prolonged hospitalization, restricted ambulation,



significant pain, and increased costs. The IBV Valve System provides a non-surgical, minimally invasive alternative to existing treatments.

The FDA HDE approval of the IBV Valve System is based on results from 58 patients enrolled in a U.S. IDE study of the device for the treatment of emphysema and four patients treated with the IBV Valve System for prolonged air leaks under IDE compassionate use exemptions. The effectiveness of the device for this use has not been demonstrated.

### **About Humanitarian Device Exemptions**

A Humanitarian Device Exemption is a U.S. Food and Drug Administration (FDA) application that is similar to a pre-market approval (PMA) application, but exempt from the effectiveness requirements of a PMA. An approved HDE authorizes marketing of a Humanitarian Use Device (HUD). An HUD is a medical device that is intended to benefit patients in the treatment or diagnosis of diseases or conditions that affect or is manifested in fewer than 4,000 individuals in the United States per year.

### **About Prolonged Air Leaks**

Air leaks are a common complication of surgery caused by lung tissue that has not completely closed and sealed, resulting in an accumulation of air in the chest that can cause breathing difficulties. As air leaks from the lung, it accumulates in the pleural cavity, making breathing difficult and interfering with normal lung expansion. Most air leaks are of small volume, are self-limited, and close naturally after a few days. In some cases they persist longer than five to seven days, at which point they become classified as prolonged. Prolonged air leaks can contribute to significant morbidity and mortality and affect outcomes after thoracic surgery.

### **About the IBV Valve System**

The IBV Valve System is a minimally invasive treatment that has diverse applications in both acute and chronic conditions of the lung. During the minimally invasive procedure, a catheter is passed through a bronchoscope (a flexible tube passed into the bronchial tubes through the mouth or nose) to deploy the small umbrella-shaped valves into the airways of the lungs. The valves are designed to be easily removed via a similar bronchoscopic procedure.

The IBV Valve System is currently under investigation in the U.S. as a new treatment option for the many people with severe emphysema who do not respond well to current medical therapies



or are not eligible for or elect not to undergo invasive surgery such as lung volume reduction or lung transplantation. The device is marketed and distributed by Olympus in Europe, where the system has received market clearance through the CE Mark for the treatment of diseased and damaged lung, an indication that includes the treatment of emphysema and the resolution of prolonged air leaks. Olympus also has development and distribution rights for the IBV Valve System in Japan.

**About Spiration, Inc.**

Spiration, Inc. is committed to improving quality of life for patients with acute and chronic conditions of the lung through the development of novel therapies. Founded in 1999 in Redmond, Wash., the privately held company is backed by prominent investors including Three Arch Partners, New Enterprise Associates, Versant Ventures, New Leaf Ventures (Sprout Group), InterWest Partners, Investor Growth Capital, Saints Capital and Olympus Medical Systems Corp. For more information, visit the company's website at [www.spiration.com](http://www.spiration.com).

Information about the U.S. pivotal study of Spiration's IBV Valve System may be found at [www.emphysematrial.com](http://www.emphysematrial.com).

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