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Blease Medical Announces FDA 510(k) Approval for Sale and Distribution of Anesthesia Systems into US Market

October 12, 2005: Hawthorne, CA

Blease Medical, a division of OSI Systems, Inc. (Nasdaq:[OSIS](#) - [News](#)), today announced that it had received 510(k) from the U.S. Food and Drug Administration ("FDA") for the sale of its Sirius 3000 with 8700 ventilator, anesthesia system into the United States market.

Currently, Blease distributes a complete range of anesthesia systems and ventilators internationally to approximately 90 countries but not currently to the United States. FDA 510(k) approval clears the way for the company's flagship system to be sold in the United States, where annual sales of anesthesia systems and ventilators is approximately \$429 million, as estimated by independent business consultants, Frost & Sullivan.

Nicholas Ong, President of Blease Medical, stated, "We are excited about achieving 510(k) certification for our Sirius 3000 with 8700 ventilator anesthesia system. Approval by the FDA helps to facilitate our marketing efforts internationally as the Sirius product line is now certified by regulatory authorities in both Europe and the United States. It is our intention to begin working towards a market launch and introduction in the United States working closely with Spacelabs Medical where possible, to leverage off their established presence and distribution network."

The FDA requires that all medical devices introduced to the U.S. be preceded either by a pre-market notification clearance order under section 510(k) of the Food, Drug and Cosmetic Act, or an approved pre-market approval application. A 510(k) pre-market notification clearance order indicates that the FDA agrees with an applicant's determination that the product for which clearance has been sought is substantially equivalent to another legally marketed medical device. The approval process to obtain certification under section 510(k) took approximately 7 months.

About Blease Medical

Blease Medical (www.blease.com), based in Chesham UK, has been a leader in anesthesia solutions for clinicians for more than 50 years. The company specializes in the design, manufacture and distribution of anesthesia systems, vaporizers and ventilators. Blease is a leading supplier of OEM products and components to the anesthesia industry worldwide. Blease products are sold internationally in anesthesia, critical care and emergency care areas. Blease operates from two UK sites and maintains a UK-based sales and service field force in addition to distribution partnerships in approximately 80 countries. Blease currently employs approximately 100 people.

About OSI Systems, Inc.

OSI Systems, Inc. is a Hawthorne, California-based diversified global developer, manufacturer and seller of security and inspection systems, medical monitoring and anesthesia products, and optoelectronic devices and value-added subsystems. The company has more than 30 years of experience in electronics engineering and manufacturing and maintains offices and production facilities located in more than a dozen countries. OSI Systems implements a strategy of expansion by leveraging its electronics and contract manufacturing capabilities into selective end product markets through organic growth

and acquisitions. For more information on OSI Systems Inc. or any of its subsidiary companies, visit www.osi-systems.com.

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements include information regarding our expectations, goals or intentions about the future, including, but not limited to, statements regarding the market acceptance of the Sirius 3000 with 8700 ventilator, anesthesia systems. The actual results may differ materially from those described in or implied by any forward-looking statement. Other important factors are set forth in our Securities and Exchange Commission filings. All forward-looking statements speak only as of the date made, and we undertake no obligation to update these forward-looking statements.

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