FOR IMMEDIATE RELEASE

SOMANETICS RECEIVES FDA 510(K) CLEARANCE TO MARKET LEFT VENTRICULAR BALLOON SIZING SYSTEM
-- Accessory for the CorRestore System - Surgical Ventricular Restoration Product --

TROY, Mich. -- March 18, 2004 -- Somanetics Corporation (Nasdaq: SMTS) announced that it has received 510(k) clearance from the U.S. Food and Drug Administration to market its Left Ventricular Balloon Sizing System in the United States.

The Left Ventricular Balloon Sizing System is designed to be used in cardiac repair and reconstruction, including an operation called Surgical Ventricular Restoration, or SVR, a surgical treatment for certain patients with severe congestive heart failure (CHF).

CHF occurs when the heart is unable to pump enough blood to meet the circulation needs of the body. One of the causes of CHF is a disease that damages the heart muscle, resulting in an enlarged ventricle. SVR is an operation that can be performed to restore more normal heart muscle function in some severe CHF patients who had a heart attack that damaged the anterior wall of their left ventricle. During SVR, the surgeon repairs the ventricle by restoring the dilated chamber to more normal size and its natural conical shape, and thus restoring more normal function. This is accomplished by opening the ventricle and inserting an implant, such as Somanetics’ CorRestore® Patch, to exclude the scarred, non-contracting segments of the heart, or by closing the defect directly.

To ensure the dilated ventricular chamber is not reduced too much during restoration, especially in ventricles that are not severely dilated, a balloon is sometimes placed in the ventricle. In the SVR operation, this is done after the left ventricle has been opened. A sterile balloon is placed into the ventricle and infused with sterile saline to ensure an adequate residual volume for the patient’s size. After the placement of sutures, the balloon is deflated and removed.

“FDA clearance of our Left Ventricular Balloon Sizing System provides us with another important instrument to help cardiac surgery patients,” stated Bruce Barrett, Somanetics’ president and chief executive officer. “We intend to include the balloon system as a value-added accessory to our CorRestore System, and offer it separately to physicians performing SVR with other patch materials or direct closure. We expect to begin marketing the accessory in May,” Barrett said.

(more)
About Somanetics

Somanetics develops and markets two medical devices focused on the cardiac surgery market that offer solutions to help meet critical medical needs. The INVOS® Cerebral Oximeter holds a unique position in U.S. hospitals as the only noninvasive and continuous monitor of changes in regional brain blood oxygen saturation that is commercially available. Use of the INVOS Cerebral Oximeter helps medical professionals, such as surgeons and anesthesiologists, identify regional brain blood oxygen imbalances and take corrective action. Such action can prevent or reduce neurological injuries related to adverse events during surgery or in the critical care unit and reduce the associated cost of care. The CorRestore System is a cardiac implant for use in cardiac repair and reconstruction, including an operation called Surgical Ventricular Restoration, SVR, a treatment for patients with certain types of severe congestive heart failure. Somanetics’ web site is www.somanetics.com.

Safe-Harbor Statement

Except for historical information contained herein, the matters discussed in this news release are forward-looking statements, the accuracy of which is necessarily subject to risks and uncertainties. Actual results may differ significantly from results discussed in the forward-looking statements. Actual results may be affected by, among other things, economic conditions in general and in the healthcare market, the demand for and market for our products in domestic and international markets, our history of losses, our current dependence on the Cerebral Oximeter and SomaSensor, the challenges associated with developing new products and obtaining regulatory approvals if necessary, research and development activities, the uncertainty of acceptance of our products by the medical community, the lengthy sales cycle for our products, third party reimbursement, competition in our markets, including the potential introduction of competitive products by others, our dependence on our distributors, physician training, enforceability and the costs of enforcement of our patents, potential infringements of our patents and the other factors set forth from time to time in Somanetics’ Securities and Exchange Commission filings, including Somanetics’ Registration Statement on Form S-1 (file no. 333-74788) effective January 11, 2002.

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