

FOR IMMEDIATE RELEASE

U-SYSTEMS' AUTOMATED BREAST ULTRASOUND PREMARKET APPROVAL APPLICATION FOR BREAST CANCER SCREENING ACCEPTED FOR FDA REVIEW

The somo•v® Automated Breast Ultrasound (ABUS) is the first ultrasound device to target screening indication

SUNNYVALE, Calif. November 10, 2011 - U-Systems, the leader in automated breast ultrasound, today announced that the U.S. Food & Drug Administration (FDA) has determined the premarket approval (PMA) application, for breast cancer screening indication for use for the somo•v® Automated Breast Ultrasound (ABUS) system, is substantially complete and acceptable for review. The somo•v ABUS system is currently FDA-cleared for diagnostic use as an adjunct to mammography.

The statistical data for the PMA submission was a result of a multi-reader, multi-case (MRMC) ROC Reader Study conducted by a team from the University of Chicago. "We are encouraged that the data included in the PMA has been accepted by the FDA for review as we strongly believe it provides a solid scientific basis for the use of breast ultrasound as an adjunctive cancer screening tool for women with dense breasts." said Maryellen Giger, Ph.D., Professor of Radiology at the University of Chicago and the Principal Investigator for the pivotal ABUS ROC Reader Study.

The ROC Reader Study cases were collected under the SOMO•INSIGHT Clinical Study, the largest trial ever undertaken by an ultrasound company. The SOMO•INSIGHT Study is designed to evaluate whether digital mammography in combination with the Automated Breast Ultrasound System is more sensitive than a routine screening mammogram alone in detecting breast cancer in women with dense breast tissue. More 16,000 women have enrolled in the study at multiple breast imaging centers nationwide.

"For most women, mammography remains the gold standard for the early detection of breast cancer, but multiple studies have demonstrated that it is not enough for women with dense breast tissue," said Rachel Brem, M.D., Professor of Radiology, Director of Breast Imaging and Intervention at the George Washington University Medical Center and the Principal Investigator of the SOMO•INSIGHT Clinical Study. "Adding automated breast ultrasound screening for women with dense breast tissue has the potential to significantly improve cancer detection rates in this population," Dr. Brem added.

"News that the FDA accepted our submission for a new indication for use of the somo•v ABUS system is very exciting for us and for many of the nation's leading breast imaging experts who were involved in the ABUS development and clinical evaluation process," said Ron Ho, president and CEO of U-Systems. "Breast density is particularly problematic as it not only impacts early detection but also carries an increased risk of breast cancer. Achieving this important FDA milestone puts us one step closer in our efforts to significantly improve the early detection of cancer in women with dense breasts."

Dense breast tissue not only increases the risk of breast cancer up to 4-6 times but also makes cancer more difficult to detect via mammography according to multiple large studies. One study, published in the New England Journal of Medicine, showed 35 percent of breast cancer goes undetected by mammography in women with dense breasts as density masks appearance of tumors (Boyd, et al, NEJM 2007:356:227-36M). As breast density goes up, the accuracy of the mammogram goes down.

Using proprietary technology to automate the breast ultrasound imaging process, the U-Systems somo•v ABUS system is ideally suited for the high-volume, screening environment. The somo•VIEWer™ Advanced 3D Workstation enables fast, accurate review and archive of patient exams, optimizing breast ultrasound screening workflow.

About U-Systems

As the leader in automated breast ultrasound technology U-Systems is establishing the standard for breast ultrasound screening. The U-Systems' sono•v Automated Breast Ultrasound (ABUS) system and sono•VIEWer Advanced 3D Workstation are cleared under 510(k) for diagnostic use as an adjunct to mammography. For more information about U-Systems, please visit our website at <http://www.u-systems.com>.

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