## The Viveve System Receives Health Canada Medical Device License to Non-Surgically Treat Vaginal Laxity Following Childbirth

## The Viveve System addresses this common unmet need in women's sexual health

May 28, 2012 Sunnyvale, California - Viveve, Inc., a woman's health company and pioneer in non-surgical vaginal tissue restoration, announces Health Canada has issued a Medical Device License for the Viveve System to treat laxity at the vaginal introitus (opening), after vaginal childbirth, to improve sexual function. The Viveve procedure is the first of its kind and the results are shown to improve the feeling of vaginal tightness and sexual satisfaction for women. "Women's sexual health concerns have not been addressed in the medical community at the same rate or with the same intensity as men's," said Dr. Gail Knudson, MD and Clinical Associate Professor at UBC Department of Sexual Medicine. "I am happy Viveve is introducing this procedure for women in Canada. I am also hoping physicians will see this as a reminder of the importance of talking to women about their overall sexual health and particularly changes in sexual health that may occur as a result of having children."

The Viveve System is a radiofrequency device that uses energy, converted to heat in the tissue, to restore collagen fibers overstretched and damaged during vaginal childbirth. The procedure is performed in a doctor's office by a trained physician, without the need for anesthesia, in approximately 30 minutes. There is no downtime and the patient can return to normal activities immediately following the procedure. "When I heard about Viveve and had the opportunity to read the data, I was very interested in this procedure," said Dr. Le Mai Tu, MD, MSc, Professor of Urology, specializing in Urogynecology, University of Sherbrooke, Quebec. "In fact, many of my patients with children who've experienced vaginal deliveries have talked to me about the vaginal anatomical changes such as laxity and its impact on their sexual satisfaction. It's encouraging that there is finally a non-invasive technology which can improve this condition and I am looking forward to learning more about the technique and introducing the Viveve procedure to my patients."

In a Viveve-sponsored survey of over 400 women, nearly half of women who responded expressed concern with laxity. In 2009, a "First in Women" Non-Significant Risk (NSR) IRB-approved study using the Viveve System was conducted in the United States. All women in the study reported an improved feeling of vaginal tightness during intercourse at one, three and six months post treatment. In addition, of the women who had experienced a decrease in sexual satisfaction at least one-year post vaginal delivery, all reported an improvement in sexual satisfaction at the one, three and sixmonth intervals. This study was published in September 2010 by the *Journal of Sexual Medicine* and can be found on the company website at <a href="www.viveve.com">www.viveve.com</a>. A second study in Japan was recently completed with similarly positive results and the three month interim report can also be found on the Viveve website.

"Canada is a very important market and we are very pleased that Health Canada has approved the Viveve System," said Kerry Pope, President and CEO of Viveve. "We are looking forward to introducing it to gynecologists and family practitioners at the upcoming SOGC Annual Clinical Meeting. Educating Canadian physicians will be a top priority for Viveve as we move ahead, so that they will be able to offer this procedure to their patients who have not had a non-surgical option for the treatment of vaginal laxity."

## **About Viveve, Inc.:**

Viveve is a privately held women's sexual health company based in Sunnyvale, California. The Viveve System is a medical device used for the non-surgical procedure of post-birth laxity of the vaginal introitus, a medically recognized quality of life condition. It is currently not available for sale in the U.S.

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The company's Series A and Series B financing was led by GBS Venture Partners and 5AM Ventures.

Viveve Inc is a currently an associate member of the Society of Obstetricians and Gynaecologists of Canada.

For more information, visit www.viveve.com.

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