



To: Our Providers & Patients:

July 31, 2018

Given the FDA's recent actions against certain companies marketing devices for vaginal rejuvenation procedures, we wanted to provide a response regarding the demonstrated safety and efficacy of our CMRF (cryogen-cooled monopolar RF) technology. Importantly, Viveve was NOT one of the seven companies included in the FDA vaginal rejuvenation safety statement and has NOT received a warning letter.

The company views the FDA statement as a positive for the industry and for Viveve since it highlights the importance of patient safety and evidence-based medicine. Our company, and our CMRF technology platform, have been built to provide safe treatments with proven clinical benefits.

Viveve currently has regulatory approvals or clearances in over 50 countries for the treatment of vaginal laxity and/or sexual function, and in Argentina for the treatment of mild urinary incontinence. We continue to pursue additional regulatory approvals documenting the safety and efficacy of our device for the treatment of gynecological and urological conditions, as demonstrated by:

- An ongoing FDA Investigational Device Exemption (IDE) trial - VIVEVE II - in the U.S. for improvement in sexual function. Clearance to start the study by FDA was based on extensive safety research, consistent with their guidance;
- The pending initiation of a clinical study - LIBERATE INTL - in Canada for treatment of SUI cleared by the Canadian Ministry of Health; and
- Submission of a SUI IDE - LIBERATE US - to FDA this quarter.

It is important to note that the FDA and other global regulatory agencies grant approvals to proceed with human clinical trials based on extensive safety testing. Viveve has completed multiple pre-clinical studies to thoroughly characterize the effect of our CMRF treatment, which clearly demonstrated that there was no injury to vaginal and surrounding tissues.

Viveve is committed to providing safe devices for use in clinical practice backed by high-quality, clinical data as evidenced by:

- Published clinical results and positive patient outcomes from a randomized, blinded, multicenter clinical trial in 2 peer-reviewed journals reporting safety and efficacy of our CMRF device for treatment of vaginal laxity and sexual function;
- Positive SUI data and 6-month interim results reported from SUI pilot and on-going feasibility studies; and
- No device-related serious adverse events reported in any clinical trials conducted or underway.

We thank you for your continuing support in our efforts to provide safe and effective treatments that address prevalent women's intimate health conditions.

Please feel free to contact us at [viveve@viveve.com](mailto:viveve@viveve.com) if you have any further questions or concerns.

Sincerely,

Scott Durbin  
Chief Executive Officer

Jim Atkinson  
President and Chief Business Officer