



GYNESONICS ANNOUNCES SUBMISSION OF FDA 510K FOR INCISION-FREE TREATMENT OF SYMPTOMATIC UTERINE FIBROIDS

Novel uterus-preserving Sonata System is first incision-free treatment to address majority of fibroids transcervically

Redwood City, CA – December 21, 2017 - Gynesonics, a women’s healthcare company focused on the development of minimally invasive solutions for uterine fibroids, today announced its submission to the FDA of its 510(k) Premarket Notification for the Sonata® System, a novel, uterus preserving, incision-free uterine fibroid treatment. The Sonata System is designed to treat fibroids transcervically with radiofrequency energy guided by an integrated intrauterine ultrasound probe.

“Submission of the 510(k) application is an important milestone for our company,” said Chris Owens, President and CEO of Gynesonics. “We are focused now on responding to any questions or requests from the FDA in support of a timely submission review, and preparations for initial commercial launch in the United States in 2018.”

Currently, only hysteroscopic myomectomy is available to treat fibroids transcervically, which in practice is limited to smaller (≤ 3 cm) submucosal fibroids. This technique is limited to approximately 15% of fibroids. Sonata is the only system designed to treat upwards of 80% of all fibroids with an incision free, uterus preserving, transcervical approach, thus providing women an important new choice over invasive surgical procedures.

“Based on the impressive 12-month results achieved in our SONATA IDE Pivotal Trial included in our FDA submission, we believe the Sonata System has the potential to be a groundbreaking treatment and a new standard of care for literally millions of women worldwide who currently have limited options for treating uterine fibroids. Sonata is the only option that can treat the majority of fibroids with a transcervical incision-free uterine-sparing approach,” explained Owens.

About Sonata System

The Sonata System, the next generation of Gynesonics’ technology platform previously referred to as VizAblate, uses radiofrequency energy to ablate fibroids under intrauterine ultrasound guidance. The Sonata® System, including the SMART Targeting Guide, enables the operator to target fibroids and optimize ablations within them. Sonata™ System’s design provides a straightforward, transcervical access for a uterus preserving, incision-free fibroid treatment. This intrauterine approach is designed to avoid the peritoneal cavity.

About Gynesonics

Gynesonics is a women's healthcare company focused on minimally invasive, uterus preserving solutions for both diagnostic and therapeutic applications. Gynesonics has developed the Sonata System for the transcervical treatment of symptomatic uterine fibroids under intrauterine ultrasound guidance. The Sonata® System is CE Marked and approved for sale in the European Union. Sonata System is not available for sale in the United States. Gynesonics is a privately held company with headquarters in Redwood City, CA.

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