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FDA Talk Paper

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FDA Approves New Device to Treat Uterine Fibroids

The Food and Drug Administration (FDA) today approved the ExAblate 2000 System, a new medical device that uses magnetic resonance image guided focused ultrasound to target and destroy uterine fibroids, non-cancerous masses located in the uterus. The device is intended to treat women who have completed child bearing or do not intend to become pregnant.

FDA expedited review of the device because it offers significant advantages over existing treatments for uterine fibroids.

ExAblate combines two systems--a magnetic resonance imaging (MRI) machine to visualize patient anatomy, map the volume of fibroid tissue to be treated, and monitor the temperature of the uterine tissue after heating, and a focused ultrasound beam that heats and destroys the fibroid tissue using high frequency, high-energy sound waves. This is the first time these two systems have been combined and the first time MR has been used to monitor tissue temperature.

The treatment requires repeated targeting and heating of fibroid tissue while the patient lies inside the MRI machine. The procedure can last as long as three hours.

The new device can be used to treat some--but not all--fibroids. Fibroids close to sensitive organs such as the bowel or bladder and those outside the image area cannot be treated.

Approximately 20 percent to 40 percent of women 35 and older have fibroids. Although many of these women do not experience any symptoms, in others the location and size of fibroids can cause heavy and prolonged menstrual periods, pain in the back, legs or pelvis, pressure on the bladder or bowels, and pain during sexual intercourse.

Women who experience problems from uterine fibroids are currently treated with hormone therapy, myomectomy (removal of the fibroids while leaving the uterus intact), or by hysterectomy (removal of the uterus). ExAblate provides a uterine-sparing alternative for these women that is a non-invasive treatment.

FDA approved the system based on a review of clinical studies of safety and effectiveness conducted by the manufacturer and on the recommendation of a panel of outside experts convened by the agency to review the device.

InSightec, Ltd., of Israel, the manufacturer, studied use of the ExAblate System to treat 109 women with uterine fibroids at seven medical centers around the world. The study compared the results with those of 82 women who had hysterectomies. When the ExAblate-treated women were followed up six months later, the study showed that the new device had successfully reduced fibroid-related problems in 71 percent. However, 21 percent of the patients needed an alternative surgical treatment for fibroids within a year.

This means that while the ExAblate treatment may succeed in reducing the symptoms from the treated fibroids, at a later time, fibroid symptoms may return in some women and require additional treatment either with ExAblate or an alternative treatment. Labeling for the device indicates that no more than two treatments should be performed in a two-week period.

The ExAblate treatment is not intended for women who desire future pregnancy. The procedure could alter the composition and strength of the uterine tissue, and the effects of the treatment on the ability to become pregnant and carry a fetus to term or on the development of the fetus have not been determined.

FDA is requiring InSightec to conduct a three-year post-market study to better assess the long-term safety and effectiveness of the ExAblate System. The study will include additional numbers of African-American women because, as a group, these women have a greater incidence of uterine fibroids, but were under-represented in the original study.

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