FDA authorizes two devices that provide real-time location of parathyroid tissue during surgery

Today, the U.S. Food and Drug Administration permitted marketing of two devices that provide real-time location of parathyroid tissue during surgical procedures such as thyroidectomy (surgery to remove all or part of the thyroid) and parathyroidectomy (surgery to remove one or more parathyroid glands).

“For some patients with parathyroid disease, treatment may mean a surgical procedure,” said Binita Ashar, M.D., director of the Division of Surgical Devices in the FDA’s Center for Devices and Radiological Health. “Real-time identification of parathyroid tissue during surgery can provide surgeons with valuable information to help preserve healthy tissue or to remove diseased tissue.”

Disorders in the parathyroid tissue, which is tissue that borders the thyroid gland, are usually treated by surgeries to remove part of the thyroid gland or parathyroid tissue. Hyperparathyroidism, or the overproduction of parathyroid hormone, is the most common of parathyroid disorders and is diagnosed in approximately 100,000 Americans each year. For surgeons treating hyperparathyroidism or other disorders, parathyroid tissue can be visually difficult to locate and distinguish from nearby tissues during a surgery.

The Fluobeam 800 Clinic Imaging Device is used to assist in the imaging of parathyroid glands and can be used as a companion method to assist surgeons in locating parathyroid tissue visually during surgery. Parathyroid tissue emits a

fluorescent glow when exposed to the device's light source, avoiding the need for a contrast agent. The device was previously cleared as an imaging system used to capture and view fluorescent images for the visual assessment of blood flow as an adjunctive method for the evaluation of tissue perfusion.

The Parathyroid Detection PTeye System aids in detecting parathyroid tissue during surgery by using a probe that emits fluorescence light. Tissue detection is based on how the parathyroid tissue reacts to the fluorescent light. When parathyroid tissue is detected, the system provides an audio and visual display to indicate its presence.

Use of either device is intended to assist, not replace, experienced visual assessment in identifying the parathyroid tissue along with a biopsy to confirm thyroid tissue per standard of care. The systems are not intended to be used to confirm the absence of parathyroid tissue or glands and are only to be used to assist the surgeon in locating potential parathyroid tissue or glands.

For the Fluobeam 800, the FDA reviewed data from five peer-reviewed published studies, including one study that compared the rate of postoperative hypocalcemia (PH), or a temporary reduction in calcium in the blood, that occurs when healthy parathyroid tissue is inadvertently removed. In 93 patients who had surgery using the device, 5 percent experienced fluctuating PH following surgery compared with 21 percent of the 153 patients who had surgery without the device.

For the PTeye System, the FDA reviewed data from a single-blinded study of 81 patients who had surgery using the device. Results demonstrated that the PTeye could correctly identify the presence of parathyroid tissue as compared to histology 93 percent of the time and correctly identify the absence of parathyroid tissue as compared to intraoperative visualization by an expert 97 percent of the time, with an overall accuracy

of 96 percent.

The Fluobeam 800 and the PTeye were reviewed separately but concurrently under the FDA’s De Novo premarket review pathway, a regulatory pathway for some low- to moderate-risk devices that are novel and for which there is no prior legally marketed device.

The FDA granted marketing authorization of The Fluobeam 800 Clinic Imaging Device to Fluoptics.

The FDA granted marketing authorization of Parathyroid Detection PTeye System to AiBiomed.

Source:

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