Ethicon Endo-Surgery Urges FDA to Grant SEDASYS® System Appeal

First computer-assisted personalized sedation system for colonoscopy and EGD procedures supported by strong clinical data and FDA Advisory Panel recommendation for approval

CINCINNATI, [November 4, 2010] - Ethicon Endo-Surgery, Inc. (EES) today urged the Office of the Commissioner of the Food and Drug Administration (FDA) to grant the company’s appeal of the Center for Devices and Radiological Health’s (CDRH) denial of the SEDASYS® System Premarket Approval Application (PMA). The SEDASYS® System is a first-of-its-kind computer-assisted personalized sedation system for colonoscopy and upper gastrointestinal (EGD) procedures. EES filed its appeal on March 26, 2010, after receiving a Not-Approvable Letter despite an 8-2 FDA Advisory Panel vote in favor of approval.

The appeal, or petition for reconsideration, is a rarely used part of the PMA process that companies can pursue when their device application is denied by one of the centers within FDA. As part of the appeals process, CDRH issued a denial letter, which EES received on October 26, 2010. The next step is for the Office of the Commissioner to grant the appeal. Granting the appeal would begin a process in which the FDA would appoint a new Independent Advisory Committee and hold a public hearing on the SEDASYS® System. Then the Commissioner would make a final decision on the application.

"We remain fully committed to working with the FDA to secure approval of the SEDASYS® System because of the potential benefits it can bring to gastroenterology patients and providers," said Karen Licitra, Company Group Chair and Worldwide Franchise Chair, EES. "Given the strong clinical data and positive panel recommendations from the FDA's Advisory Panel, we are disappointed the agency has not approved the SEDASYS® System. We have been in conversations with the FDA for several months and believe appealing to the Commissioner's Office is our best path forward to ensure a thorough reconsideration of the SEDASYS® System clinical trial data and application."

The SEDASYS® System was designed in collaboration with anesthesiologists, clinical pharmacologists and anesthesia device experts for physician/nurse teams to provide minimal-to-moderate sedation with propofol during colonoscopy and esophagogastroduodenoscopy (EGD) procedures. The system integrates physiological patient monitoring with personalized drug delivery and is designed to maximize patient safety. EES believes the device, if approved, may help reduce sedation-related risks associated with colonoscopies, improve the overall patient experience, and encourage more individuals to be screened for colon cancer, which kills more than 50,000 Americans each year.

Outside the U.S., the SEDASYS® System has been granted a CE Mark for the European Union and approved in Australia for colonoscopy and EGD procedures. Health Canada also granted regulatory approval for the SEDASYS® System for use by healthcare professional teams during routine colonoscopies.

System Design, Clinical Data and Training

The SEDASYS® System automatically detects and responds to signs of over-sedation (oxygen desaturation and low respiratory rate/apnea), based on continual monitoring and recording of critical patient vital signs, including oxygen saturation, respiratory rate, heart rate, blood pressure, end-tidal carbon dioxide and patient responsiveness.

In the 1,000-patient clinical trial, those who received sedation with the SEDASYS® System experienced fewer and less significant oxygen desaturation events, a clinical sign of over-sedation, than patients sedated with the current standard of care drugs-benzodiazepines and opioids.

Gastroenterologists are highly trained specialists who safely sedate more than 12 million Americans undergoing endoscopy procedures every year. The pivotal study data showed that trained gastroenterologist/nurse teams were able to precisely titrate propofol for minimal-to-moderate sedation via the SEDASYS® System to patients undergoing routine colonoscopy and EGD procedures.

Labeling and Intended Users

Propofol is a preferred sedative due to its rapid onset and facilitation of quick, clear-headed recovery, which enables patients to promptly return to normal activities. Current propofol drug labeling states only persons trained in the administration of general anesthesia should administer the drug. In the majority of practice settings, however, gastroenterologists do not have broad access to anesthesiologists. FDA policy allows for medical device labeling to differ from the approved drug label if certain conditions related to indications, route of administration and dosage are met. The SEDASYS® System meets these conditions.
The company's desired labeling for the SEDASYS® System would allow gastroenterologist and nurse teams to administer propofol without an anesthesia professional. EES believes that the clinical data supports the proposed labeling. In fact, an independent FDA Advisory Panel agreed with EES when it voted 9-1 that physician/nurse teams using the SEDASYS® System do not have to be trained in the administration of general anesthesia.

Clinical Study Results

The PMA submission was based upon the results of the clinical study. The study was a multi-center, prospective, randomized, controlled trial with 1,000 patients—a large sample size for a PMA device study—that evaluated the SEDASYS® System versus the current standard of care - benzodiazepines and opioids - for sedation during endoscopic procedures (colonoscopy and EGD). This study was designed in collaboration with the FDA and subsequently approved by the agency.

This study design took into account real-world clinical practice in which the majority of sedation for routine endoscopy procedures is performed by a gastroenterologist. The previous Advisory Panel carefully considered the design of the pivotal trial and concluded by a margin of 8-2 that EES used the appropriate control group.

- Results showed that patients who received sedation with the SEDASYS® System experienced fewer and less significant oxygen desaturation events than patients sedated with the current standard of care.
- The study showed that trained gastroenterologist/nurse teams were able to titrate propofol with the SEDASYS System to provide minimum-to-moderate sedation, ideal for non-emergent endoscopic procedures.
- Patients sedated during the clinical study with the SEDASYS® System experienced no serious adverse events, rescue interventions, or device-related adverse events.
- One hypoxemia adverse event occurred in the SEDASYS® System group compared to 27 events in the current standard of care group.
- Of the patients that received sedation with the SEDASYS® System, five (1 percent) experienced transient general anesthesia. The five patients who experienced transient general anesthesia did not experience hypoxemia or apnea. These patients did not experience any sedation-related or device-related adverse events and completed the procedure successfully.
- Patients receiving sedation with the SEDASYS® System recovered from sedation twice as fast as patients receiving the current standard of care for sedation, with 99 percent of patients using the SEDASYS® System recovering from sedation within 10 minutes.
- Clinicians were significantly more satisfied with the sedation achieved with the SEDASYS® System versus the current standard of care.

Potential Economic Benefits of SEDASYS® System

Anesthesia-professional delivered sedation in routine endoscopic procedures is projected to increase substantially in the coming years, potentially exceeding $5 billion in part due to provider preference for the sedative propofol. A recent study indicated that computer-assisted personalized sedation (CAPS), such as the SEDASYS® System, could lead to substantial cost savings for endoscopic procedures. Projected cost savings in 2015 for a single health plan could total approximately $163M for colonoscopy and $131M for EGD, if CAPS were used in 80% of procedures that utilize an anesthesiologist.

About the SEDASYS® System

The SEDASYS® System is the first computer-assisted personalized sedation (CAPS) system designed for physician/nurse teams to provide minimal-to-moderate sedation with propofol. By integrating state-of-the-art drug delivery and patient monitoring, the SEDASYS® System enables physician/nurse teams to deliver personalized sedation. It automatically detects and responds to signs of over-sedation (oxygen desaturation and low respiratory rate/apnea) by stopping or reducing delivery of propofol, increasing oxygen delivery and automatically instructing patients to take a deep breath. The SEDASYS® System monitors and records patient vital signs and additional parameters, including oxygen saturation, respiratory rate, heart rate, blood pressure, end-tidal carbon dioxide and patient responsiveness. The device is currently an investigational device limited by U.S. law to investigational use only.

About Ethicon Endo-Surgery

Ethicon Endo-Surgery, a Johnson & Johnson company, develops and markets advanced medical devices for minimally invasive and open surgical procedures, focusing on procedure-enabling devices for the interventional diagnosis and treatment of conditions in general and bariatric surgery, as well as gastrointestinal health, gynecology and surgical oncology. More information can be found at www.ethiconendosurgery.com.

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