2009-4438q1

FDA Questions

2009-443891

**FDA Questions for Anesthesiology and Respiratory Therapy Devices Advisory Panel**

**May 28, 2009**
**P080009**

**Ethicon Endo-Surgery SEDASYS™**

1. Please discuss what duration and degree of anesthesia/deep sedation and/or hypoxemia may be considered safe under the proposed conditions of use for the SEDASYS device.
   a. Please discuss the risk of periods of unintended deep sedation and/or general anesthesia associated with propofol when administered using SEDASYS, including those observed in the pivotal study.

   b. Please discuss the oxygen desaturation events associated with propofol when administered using SEDASYS, including those observed during the pivotal study.

2. Please discuss how the management of hypoxemic events at some of the study sites impacts the evaluation of the primary study endpoint, and what implications this could have for the actual clinical use of the SEDASYS device.

| Primary Endpoint Colonoscopy | SEDASYS System | Current Standard of Care |
|---|---|---|
| AUC: Mean (%*seconds) ± SD | 17.8 ± 124.59 | 98.8 ± 510.32 |

3. Please discuss whether evaluation of the applicant's data constitute reasonable assurance that the SEDASYS device, will enable safe and effective use of *propofol* in the procedures described when administered by:

   - persons who are not trained in the administration of general anesthesia.

   - persons who have been trained in the administration of general anesthesia and are not involved in the procedure.

4. Please discuss the appropriateness of the pivotal study control arm and how the study design affected interpretation of the study findings (i.e. use of SEDASYS by healthcare providers who are or are not trained in general anesthesia).

5. If SEDASYS were to be approved, discuss what postmarketing studies should be conducted.
    a. Should studies include adjustments so that the effect of gender can be evaluated for safety and effectiveness of the device?
    b. How would you expect provider/site procedure volume and experience to affect the generalizability of safety and effectiveness results in a post-approval study?
    c. Should studies assess the safety of bolus-dosing feature?
    d. Are there other short or long-term safety concerns that you think should be addressed?

DRAFT