DRAFT Discussion Questions for LAP-BAND® Panel

The LAP-BAND® is currently indicated for patients with severe obesity [Body Mass Index (BMI) of at least 40 kg/m^2 or a BMI of at least 35 kg/m^2 with one or more severe comorbid conditions, or for those who are 100 pounds over their estimated ideal weight (midpoint of the Met Life Tables)]. The sponsor is now proposing to modify the indication to include obese patients with a BMI of at least 35kg/m^2 or a BMI of at least 30 kg/m^2 with one or more comorbid conditions. In summary, these changes now include:

a. Removal of the need for a comorbid condition in patients with a BMI between 35 kg/m^2 and 40 kg/m^2, and

b. Expansion of the use of the LAP-BAND® to patients with a BMI between 30 kg/m^2 and 35 kg/m^2 with associated comorbid conditions.

1. Please discuss whether the data support the proposed changes in the Indication for Use for the LAP-BAND® , taking into consideration the following issues:

   a. The primary effectiveness endpoint required greater than 40% of subjects to achieve clinically successful weight loss at 12 months after LAP-BAND® implantation, where success was defined as at least a 30% excess weight loss. For those subjects in the lower BMI, the amount of weight needed to be a 'success' was lower than that of the subjects in higher BMI cohorts. For those subjects with a BMI of 30-35 kg/m^2, please discuss whether the data support this change in Indication for Use in that the success criteria were skewed in favor of this group.

   b. In the previous LAP-BAND® study and in the literature, the majority of patients enrolled in weight loss studies have been women. In the current study assessing weight loss in lower BMI patients, only 14 of the 149 patients were male and the majority (77%) of the patients were Caucasian. Please discuss whether there are concerns about the limited data available on males and other under-represented demographics in the current study for this indication.

2. FDA has reviewed the Guidelines from several professional societies whose members guide medical and/or surgical therapies for the treatment of obesity. The Society of American Gastrointestinal and Endoscopic Surgeons, NIH Guidelines, the American Society of Clinical Endocrinologists, and the American Society for Metabolic and Bariatric Surgery generally recommend surgical intervention for those subjects with a BMI over 35 kg/m^2. If this PMA is approved, these guidelines may have to be modified as they are accepted as the "standard of care" for obesity surgery. Please discuss the modified labeling for the use of this device in the context of changing the practice of medicine for the 30-35 kg/m^2 BMI patient population.

3. FDA's inclusion of discussion on a Post-approval study (PAS) should not be interpreted to mean that FDA has made a decision on the approvability of this PMA. The presence of post-approval study plans or commitments does not in any way alter the requirements for premarket approval. A recommendation from the Panel on whether the data demonstrates

reasonable assurance on device safety and effectiveness must be based solely on the premarket data. Regarding the proposed PAS for the lower BMI patient, the sponsor has proposed a prospective study to evaluate the safety and effectiveness of the 149 patients enrolled in the IDE study for up to five years post-implantation. Please discuss the appropriateness of the proposed study addressing the following:

a. Please discuss whether the patient population of 149 IDE subjects is appropriate for generalizing the long-term results to the patient population who may use this device.

b. Please discuss if there is need for a study to evaluate device performance in the post market setting with enrollment of new subjects.

c. The sponsor proposes to evaluate the primary effectiveness at year five with the following criterion; "*The percent of subjects treated with the LAP-BAND® who achieve successful weight loss, at five years post- implantation, will be statistically greater than 40%, where successful weight loss is defined as at least 30% Excess Weight Loss (EWL).*" Please discuss whether this criterion is appropriate for the evaluation of the effectiveness of the LAP-BAND®.

d. The sponsor proposes to assess safety of the LAP-BAND® without providing specific safety endpoints. Please discuss the specific endpoints which would be the most important in assessing the long-term safety of the LAP-BAND® in lower BMI patients.

Voting Questions for LAP-BAND® Panel:

The proposed indications for use statement for the LAP-BAND® Adjustable Gastric Banding System " The LAP-BAND® System is indicated for use in weight reduction for obese patients with a Body Mass Index (BMI) of at least 35kg/m^2 or a BMI of at least 30 kg/m^2 with one or more comorbid conditions. It is indicated for use in obese adult patients who have failed more conservative weight reduction alternatives, such as supervised diet, exercise and behavior modification programs. Patients who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives." Please discuss whether there is valid scientific evidence to support this statement. If not, please discuss possible changes to the statement and whether there is valid scientific evidence to support those changes.

Following the panel discussion, CDRH will ask panel members to vote by ballot on the following three questions:

The following questions relate to the approvability of the LAP-BAND® Adjustable Gastric Banding System. Please answer them based on your expertise, the information you reviewed in preparation for this meeting, and the information presented today:

1. Is there a reasonable assurance that the LAP-BAND® is safe for use in weight reduction for obese patients with a BMI of at least 35kg/m^2 or a BMI of at least 30 kg/m^2 with one or more comorbid conditions?

2. Is there a reasonable assurance that the LAP-BAND® is effective for use in weight reduction for obese patients with a BMI of at least 35kg/m^2 or a BMI of at least 30 kg/m^2 with one or more comorbid conditions?

3. Do the benefits of the LAP-BAND® for the stated indication outweigh the risks of the LAP-BAND® for use in weight reduction for obese patients with a BMI of at least 35kg/m^2 or a BMI of at least 30 kg/m^2 with one or more comorbid conditions, for purposes of approval?