

Voting Questions

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee

February 25, 2016

Premarket Application: (P140006) ASTORA Women's Health, LLC
Endo Pharmaceuticals, Inc.

TOPAS™ Treatment for Fecal Incontinence

The sponsor has proposed the following Indications for Use:

The TOPAS Treatment for Fecal Incontinence is intended to treat women with fecal incontinence (also referred to as accidental bowel leakage) who have failed more conservative therapies.

The following questions relate to the approvability of the TOPAS Device. Please answer them based on your expertise, the information you reviewed in preparation for this meeting, and the information presented today.

Voting Question 1:

Is there reasonable assurance that the TOPAS device is safe for patients who meet the criteria specified in the proposed indication?

Voting Question 2:

Is there reasonable assurance that TOPAS device is effective for use in patients who meet the criteria specified in the proposed indication?

Voting Question 3:

Do the benefits of the TOPAS device outweigh the risks for use in patients who meet the criteria specified in the proposed indication?

Panel members will be asked to state how they answered each question and to explain their answers.