FOOD AND DRUG ADMINISTRATION (FDA)
Office of the Commissioner (OC)

Meeting of the Pediatric Advisory Committee (PAC)
September 17, 2021

QUESTIONS FOR THE COMMITTEE

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1. **VOTE:** Recurrent improper use of device was observed in the new serious adverse events. Also, the attractive force of the magnet increases as the distance is reduced. Does the committee agree that additional warnings about improper device use, including excess user manipulations of the device, and explanation of the magnet behavior would address and mitigate the risk of perforations or TEFs?

2. **VOTE:** There are multiple clinical factors that can impact the effectiveness of the anastomosis. Does the committee agree that physicians should be given additional information regarding the clinical variables to better identify suitable candidates for treatment with the Flourish device?

3. **VOTE:** The FDA will report on the following to the PAC in 2022:
    - Annual distribution number
    - PAS follow-up results
    - MDR review
    - Literature review

    Does the Committee agree with the FDA's plan for continued surveillance of the Flourish device?