Elana Surgical Kit

HDE: H080005

Office of Device Evaluation Center for Devices and Radiological Health

Pediatric Advisory Committee

September 14, 2016

ANNUAL UPDATE

- We are unaware of sales or use of this device since the last PAC meeting.
- There have been no MDRs reported associated with this device.
- There have been no new scholarly publications involving human subjects since the last PAC meeting.

- **FDA's Review Team has identified no new safety concerns since September 2015's PAC meeting.**
- **FDA concludes that the probable benefit/risk profile of the device for the pediatric population continues to support the HDE.**
- **The Mandated Post-Approval Study has been put on hold due to non use in the United States. Should device use resume the study will be reinstated.**

FDA Recommendation

FDA will continue surveillance and report the following to the PAC in 2017:

- MDR Review
- Mandated Post-Approval Study Review
- Literature Review

QUESTION TO THE PAC

Does the Committee agree with FDA's conclusions and proposed approach?