U.S. FOOD & DRUG ADMINISTRATION

Elana Surgical Kit
H080005

Presentation to the Pediatric Advisory Committee
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ANNUAL UPDATE

- We are unaware of sales or use of this device since the last PAC meeting
- There have been no Medical Device Reports (MDR) associated with this device
- There have been no new scholarly publications since the last PAC meeting

CONCLUSIONS

- FDA's Review Team has identified no new safety concerns since September 2016'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 Recommendations

FDA will continue surveillance and report the following to the PAC in 2018:

- Annual Distribution Number (ADN)
- MDR Review
- Literature Review
- Mandated Post-Approval Study Review

Question to the PAC

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


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