

Meeting of the General Hospital and Personal Use Devices Advisory Committee

Reducing the Risk of Infection from Reprocessed Duodenoscopes

Panel Deliberation Questions

Question



1. Considering the currently available MDR data and postmarket surveillance data, as well as the challenges with implementation of new reprocessing methods and adoption of new technologies, does the panel recommend
 - continued incremental improvements (e.g., disposable endcap duodenoscopes, release of newly validated reprocessing instructions) to improve the safety of reprocessed duodenoscopes versus
 - more substantial changes to duodenoscopes and reprocessing methods?

Question



2. Does the panel have comments on FDA's proposal to standardize duodenoscope durability testing to include 250 cycles of simulated use, cleaning, high level disinfection, and terminal sterilization?

Question



3a. The panel is asked to comment on the potential for new designs to reduce the observed contamination rate with reprocessed duodenoscopes, and the urgency with which the transition to new duodenoscopes should be made.

Question



3b. For technologies that are intended to reduce contamination rates for duodenoscopes, what is the appropriate balance between demonstrating the effectiveness of the technology prior to marketing, versus the benefit of having the technology available for use?

Question



4. Does high-level disinfection provide an adequate margin of safety? Considering the challenges and benefits of sterilization for routine duodenoscope reprocessing, is a transition towards sterilization warranted, and if so, how can the inherent challenges with sterilization be addressed?

