

**Draft Questions for Panel
Middle Ear Inflation Devices
Including Product Code:
MJV – Middle Ear Inflation Devices**

1. FDA has identified the following risks to health for middle ear inflation devices under product code “MJV,” based upon FDA’s review of literature, information available to FDA regarding the cleared devices, and the Manufacturer and User facility Device Experience (MAUDE) database:

- Air embolism due to uncontrolled air pressure and volume

Please comment on whether you agree with inclusion of all of the risks in the overall risk assessment of the middle ear inflation devices under product code “MJV.” In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these middle ear inflation devices.

2. Section 513 of the Food, Drug, and Cosmetic Act states a device should be Class III if:
 - insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls would provide such assurance, AND
 - the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

A device should be Class II if:

- general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness, AND
- there is sufficient information to establish special controls to provide such assurance.

A device should be Class I if:

- general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
- insufficient information exists to:
 - determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
 - establish special controls to provide such assurance, BUT

- I. is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, AND
- II. does not present a potential unreasonable risk of illness or injury.

FDA does not believe that special controls will be required for middle ear inflation devices under product code “MJV” and that general controls will be sufficient to provide a reasonable assurance of the safety and effectiveness of the middle ear inflation devices. As such, FDA believes that Class I is the appropriate classification for the middle ear inflation device under product code “MJV.”

Please discuss whether you agree with FDA’s proposed classification of Class I with general controls for middle ear inflation devices under product code “MJV.” If you do not agree with FDA’s proposed classification, please provide your rationale for recommending a different classification.