



Pediatric Device Issues Update

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Outline

- FDAISA implementation
- Guidance development
- OSEL activities
- Other activities
- Looking ahead

FDAISA Implementation

- Pediatric Rare Diseases Workshop
- HDE Guidance
- Custom Devices Guidance
- Pediatric Device Consortia

Guidance Development

- Pediatric Tracking Rule and Guidance
- Extrapolation of Adult data Guidance
- Pediatric Information for X-ray Premarket notification

OSEL Activities

- Dosing Devices
- Thermometers

Other Activities

- Federal SIDS Initiative
- Pediatric Advisory Committee
- Decorative contact lens initiative



Looking
Ahead