CDRH Proposed Guidances for Fiscal Year 2026

See CDRH Proposed Guidance Development for more information about these lists.

A-List

Final Guidance Topics

- Validation of Diagnostic Tests for Emerging Pathogens following a Declaration and Determination under Section 564
- Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices
- Predetermined Change Control Plans for Medical Devices
- Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle (title changed from "Patient Preference Information - Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling")

Draft Guidance Topics

- Enforcement Discretion Policy for Premarket and Other Requirements for NIOSH-Approved Air Purifying Respirators
- Menstrual Products – Labeling and Performance Testing Recommendations (title changed from "Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s)")
- Quality Management System Information for Certain Premarket Submission Reviews
- Policy for Device Software Functions (title changed from "Policy for Device Software Functions and Mobile Medical Applications")

B-List

Final Guidance Topics

- Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management Considerations and Marketing Submission Recommendations
- Medical Devices with Indications Associated with Weight Loss – Premarket Considerations
- Content of Human Factors Information in Medical Device Marketing Submissions

Draft Guidance Topics

- None

Under Construction List

- Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission
- Clinical Evidence Considerations for Digital Mental Health Treatment Devices, including Computerized Behavioral Therapy Devices
- Evaluation of Thermal Effects of Medical Devices that Produce Tissue Heating and/or Cooling
- Evidentiary Expectations for 510(k) Implant Devices
- General/Specific Intended Use
- Pulse Oximeters – Assessing Clinical and Scientific Evidence (title changed from “Pulse Oximeters - Premarket Notification Submissions [510(k)s]”)
- Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions
- Robotically-Assisted Surgical Devices
- Substantial Equivalence with Limitations: 510(k) Devices (title changed from “Determination of Intended Use for 510(k) Devices”)