

CDRH Proposed Guidances for Fiscal Year 2027

See [CDRH Proposed Guidance Development](#) for more information about these lists.

A-List

Final Guidance Topics

- Compliance Policy Regarding Premarket and Other Requirements for Certain NIOSH Approved Air-Purifying Respirators
- Marketing Submission and Lifecycle Management Recommendations for Artificial Intelligence-Enabled Device Software Functions
- Menstrual Products: Performance Testing & Labeling Recommendations
- Predetermined Change Control Plans for Medical Devices
- Quality Management System Information for Certain Premarket Application Reviews
- Robotically-Assisted Surgical Devices - Premarket Submissions
- The Accreditation Scheme for Conformity Assessment (ASCA) Program guidances

Draft Guidance Topics

- Generative Artificial Intelligence-Enabled Conversational Devices for Mental Disorders: Evidentiary Recommendations

B-List

Final Guidance Topics

- Medical Device User Fee Small Business Qualification and Determination
- Pulse Oximeters for Medical Purposes - Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations
- Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program

Draft Guidance Topics

- Policy for Device Software Functions (title changed from “Policy for Device Software Functions and Mobile Medical Applications”)
- Postmarket Management of Cybersecurity in Medical Devices

Under Construction List

- Considerations for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission
- Evaluation of Thermal Effects of Medical Devices that Produce Tissue Heating and/or Cooling
- Risk Assessment and Evidentiary Considerations for Generative Artificial Intelligence-Enabled Devices
- Select Updates for the 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]