



**FDA** U.S. FOOD & DRUG  
ADMINISTRATION

# **FY 2025**

## ***Real Time Report***

*pursuant to the*

## **Federal Food, Drug, and Cosmetic Act**

*as amended by the Medical Device User Fee Amendments of  
2022*

## ***Acronyms***

**FD&C Act** – Federal Food, Drug, and Cosmetic Act

**FDA** – Food and Drug Administration

**FDAUFRA 2022** – FDA User Fee Reauthorization Act of 2022

**FY** – Fiscal Year (October 1 to September 30)

**MDUFA** – Medical Device User Fee Amendments

**Q1** – Quarter 1 (October 1 to December 31)

**Q2** – Quarter 2 (January 1 to March 31)

**Q3** – Quarter 3 (April 1 to June 30)

**Q4** – Quarter 4 (July 1 to September 30)

## ***Background***

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On September 30, 2022, the FDA User Fee Reauthorization Act of 2022 (FDAUFRA)) (Public Law 117-180) was signed into law. FDAUFRA 2022 amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by revising and extending the user fee programs for human drugs, biologics, generic drugs, medical devices, and biosimilar biological products.

Section 738A(a)(1)(A)(iii) of the FD&C Act, as amended by section 2004 of FDAUFRA 2022, requires the Food and Drug Administration (FDA) to provide “Real Time” reporting, posted on a quarterly basis, of guidance documents and public meetings related to the process for the review of devices.

### **Real Time Reporting Under Section 738A(a)(1)(A)(iii) of the FD&C Act**

This report is being issued pursuant to the requirement of section 738A(a)(1)(A)(iii) of the FD&C Act, which states:

“Not later than 30 calendar days after the end of the second quarter of fiscal year 2023, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary [of Health and Human Services] shall post...on the internet website of the Food and Drug Administration...

- “The number and titles of draft and final guidance on topics related to the process for the review of devices, and whether such guidance’s were issued as required by statute or pursuant to the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022; and
- “The number and titles of public meetings held on topics related to the process for the review of devices, and if such meetings were required by statute or pursuant to a commitment under the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022.”

# Medical Devices

## Summary

This section provides a summary of the total numbers for each category contained in this report, for certain activities as they relate to the process for the review of devices, within the current fiscal year (FY) as of September 30, 2025.

**Table 1: Total Number of Guidance Documents and Public Meetings as of September 30, 2025**

Category	Total
Guidance Documents	33
Public Meetings	2

## Guidance Documents

Pursuant to the MDUFA V Commitment Letter,<sup>1</sup> the table below includes all FDA guidance documents issued in FY 2025 related to the devices program. Pursuant to section 738A(a)(1)(A)(iii) of the FD&C Act, guidance documents that are related to the process for the review of devices and whether they are required by statute or are being issued pursuant to the MDUFA V Commitment Letter are indicated as such.<sup>2</sup> The table also indicates whether a guidance document is on the Center for Devices and Radiological Health’s annual agenda of guidance documents (known as the A/B List).<sup>3</sup> Guidance documents are listed by the quarter in which they were issued and are provided in a cumulative format for FY 2025.

**Table 2: Draft and Final Guidance Documents Related to the Devices Program for FY 2025**

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
1	Q1	Endosseous Dental Implants and Endosseous Dental Implant Abutments - Performance Criteria for Safety and Performance Based Pathway <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/endosseous-dental-implants-and-endosseous-dental-implant-abutments-performance-criteria-safety-and">www.fda.gov/regulatory-information/search-fda-guidance-documents/endosseous-dental-implants-and-endosseous-dental-implant-abutments-performance-criteria-safety-and</a>	10/15/2024	Yes	No	N/A	No

<sup>1</sup> [www.fda.gov/media/158308/download](http://www.fda.gov/media/158308/download).

<sup>2</sup> CDRH provides the annotation of “yes” for guidance’s that are substantially related to the process. CDRH provides the annotation of “no” for guidance’s that contain a minimal amount of guidance related to the process.

<sup>3</sup> [CDRH Proposed Guidance Development | FDA](#)

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
2	Q1	Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-long-term-clinical-neurodevelopmental-safety-studies-neonatal-product-development">www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-long-term-clinical-neurodevelopmental-safety-studies-neonatal-product-development</a>	10/18/2024	Yes	No	N/A	No
3	Q1	510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program-and-third-party-emergency-use-authorization-eua-review">www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program-and-third-party-emergency-use-authorization-eua-review</a>	11/21/2024	No	Yes	Section 2502 of the Food and Drug Omnibus Reform Act (FDORA)	A-List
4	Q1	Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-metallic-bone-screws-and-washers-performance-criteria-safety-and-performance">www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-metallic-bone-screws-and-washers-performance-criteria-safety-and-performance</a>	11/22/2024	Yes	No	N/A	No
5	Q1	<sup>4</sup> Orthopedic Non-Spinal Bone Plates, Screws, and Washers - Premarket Notification (510(k)) Submissions <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-bone-plates-screws-and-washers-premarket-notification-510k-submissions">www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-bone-plates-screws-and-washers-premarket-notification-510k-submissions</a>	11/22/2024	Yes	No	N/A	No
6	Q1	<sup>5</sup> Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/transitional-enforcement-policy-ethylene-oxide-sterilization-facility-changes-class-iii-devices">www.fda.gov/regulatory-information/search-fda-guidance-documents/transitional-enforcement-policy-ethylene-oxide-sterilization-facility-changes-class-iii-devices</a>	11/26/2024	Yes	No	N/A	No
7	Q1	Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence">www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence</a>	12/04/2024	Yes	No	N/A	A-List
8	Q1	<sup>4</sup> Global Unique Device Identification Database (GUDID) <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/global-unique-device-identification-database-gudid">www.fda.gov/regulatory-information/search-fda-guidance-documents/global-unique-device-identification-database-gudid</a>	12/17/2024	No	No	N/A	No

<sup>4</sup> This is a Level 2 guidance document as defined in 21 CFR 10.115(c)(2)

<sup>5</sup> This is a Level 1 guidance document that is immediately in effect as defined in section 701(h)(1)(C) of the FD&C Act and 21 CFR 10.115(g)(2).

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
9	Q1	Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/protocol-deviations-clinical-investigations-drugs-biological-products-and-devices">www.fda.gov/regulatory-information/search-fda-guidance-documents/protocol-deviations-clinical-investigations-drugs-biological-products-and-devices</a>	12/30/2024	Yes	No	N/A	No
10	Q2	Study of Sex Differences in the Clinical Evaluation of Medical Products <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/study-sex-differences-clinical-evaluation-medical-products">www.fda.gov/regulatory-information/search-fda-guidance-documents/study-sex-differences-clinical-evaluation-medical-products</a>	01/07/2025	Yes	No	N/A	No
11	Q2	Validation of Certain In Vitro Diagnostic Devices for Emerging Pathogens During a Section 564 Declared Emergency <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/validation-certain-in-vitro-diagnostic-devices-emerging-pathogens-during-section-564-declared-emergency">www.fda.gov/regulatory-information/search-fda-guidance-documents/validation-certain-in-vitro-diagnostic-devices-emerging-pathogens-during-section-564-declared-emergency</a>	01/07/2025	No	No	N/A	No
12	Q2	Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/communications-firms-health-care-providers-regarding-scientific-information-unapproved-uses">www.fda.gov/regulatory-information/search-fda-guidance-documents/communications-firms-health-care-providers-regarding-scientific-information-unapproved-uses</a>	01/07/2025	No	No	N/A	No
13	Q2	Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological">www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological</a>	01/07/2025	Yes	No	N/A	No
14	Q2	Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/artificial-intelligence-enabled-device-software-functions-lifecycle-management-and-marketing">www.fda.gov/regulatory-information/search-fda-guidance-documents/artificial-intelligence-enabled-device-software-functions-lifecycle-management-and-marketing</a>	01/07/2025	Yes	No	N/A	A-List
15	Q2	Pulse Oximeters for Medical Purposes - Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-medical-purposes-non-clinical-and-clinical-performance-testing-labeling-and">www.fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-medical-purposes-non-clinical-and-clinical-performance-testing-labeling-and</a>	01/07/2025	Yes	No	N/A	A-List

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
16	Q2	Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc">www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc</a>	01/07/2025	No	Yes	Section 2514 of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act	No
17	Q2	Developing Drugs for Optical Imaging <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-drugs-optical-imaging">www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-drugs-optical-imaging</a>	01/08/2025	Yes	No	N/A	No
18	Q2	<sup>4</sup> Premarket Approval Application and Humanitarian Device Exemption Modular Review <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-approval-application-and-humanitarian-device-exemption-modular-review">www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-approval-application-and-humanitarian-device-exemption-modular-review</a>	01/13/2025	Yes	No	N/A	No
19	Q2	<sup>4</sup> Institutional Review Board (IRB) Written Procedures <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-board-irb-written-procedures">www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-board-irb-written-procedures</a>	02/05/2025	No	No	N/A	No
20	Q2	<sup>4</sup> Data Standards Catalog <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog">www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog</a>	03/24/2025	Yes	No	N/A	No
21	Q2	<sup>4</sup> Evaluation of Sex-Specific Data in Medical Device Clinical Studies - Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/evaluation-sex-specific-data-medical-device-clinical-studies-guidance-industry-and-food-and-drug">www.fda.gov/regulatory-information/search-fda-guidance-documents/evaluation-sex-specific-data-medical-device-clinical-studies-guidance-industry-and-food-and-drug</a>	03/31/2025	Yes	No	N/A	No
22	Q3	Electronic Submission Template for Medical Device Q-Submissions <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-q-submissions">www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-q-submissions</a>	05/29/2025	Yes	Yes	745A(b) of the FD&C Act	No
23	Q3	Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program">www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program</a>	05/29/2025	Yes	Yes	MDUFA V Commitment Letter II.A.	A-List

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
24	Q3	Transfer of a Premarket Notification (510(k)) Clearance – Questions and Answers <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/transfer-premarket-notification-510k-clearance-questions-and-answers">www.fda.gov/regulatory-information/search-fda-guidance-documents/transfer-premarket-notification-510k-clearance-questions-and-answers</a>	06/05/2025	Yes	No	N/A	No
25	Q3	Hernia Mesh – Package Labeling Recommendations <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/hernia-mesh-package-labeling-recommendations">www.fda.gov/regulatory-information/search-fda-guidance-documents/hernia-mesh-package-labeling-recommendations</a>	06/06/2025	Yes	No	N/A	No
26	Q3	Conducting Remote Regulatory Assessments Questions and Answers <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-remote-regulatory-assessments-questions-and-answers">www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-remote-regulatory-assessments-questions-and-answers</a>	06/26/2025	Yes	No	N/A	No
27	Q3	Unique Device Identifier Requirements for Combination Products <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identifier-requirements-combination-products">www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identifier-requirements-combination-products</a>	06/26/2025	No	No	N/A	No
28	Q3	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-system-considerations-and-content-premarket-submissions">www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-system-considerations-and-content-premarket-submissions</a>	06/27/2025	Yes	No	N/A	A-List
29	Q4	Medical Device User Fee Small Business Qualification and Determination <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-determination">www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-determination</a>	07/31/2025	Yes	No	N/A	A-List
30	Q4	<sup>4</sup> Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence">www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence</a>	08/18/2025	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
31	Q4	Animal Studies for Dental Bone Grafting Material Devices - Premarket Notification (510(k)) Submissions <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/animal-studies-dental-bone-grafting-material-devices-premarket-notification-510k-submissions">www.fda.gov/regulatory-information/search-fda-guidance-documents/animal-studies-dental-bone-grafting-material-devices-premarket-notification-510k-submissions</a>	08/22/2025	Yes	No	N/A	No
32	Q4	Consideration of Enforcement Policies for In Vitro Diagnostic Tests During a Section 564 Declared Emergency <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/consideration-enforcement-policies-in-vitro-diagnostic-tests-during-section-564-declared-emergency">www.fda.gov/regulatory-information/search-fda-guidance-documents/consideration-enforcement-policies-in-vitro-diagnostic-tests-during-section-564-declared-emergency</a>	09/23/2025	No	No	N/A	A-List
33	Q4	Computer Software Assurance for Production and Quality System Software <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-system-software-0">www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-system-software-0</a>	09/24/2025	No	No	N/A	B-List

## Public Meetings

Pursuant to section 738A(a)(1)(A)(iii) of the FD&C Act, public meetings that are related to the process for the review of devices are listed in the table below.

**Table 3: Public Meetings Held on Topics Related to the Process for the Review of Devices for FY 2025**

#	Quarter Held	Title	Date Held	Required by Statute or Commitment Letter
1	Q4	Reauthorization of the Medical Device User Fee Amendments <a href="http://www.fda.gov/medical-devices/medical-devices-news-and-events/register-fdas-public-meeting-reauthorization-medical-device-user-fee-amendments-08042025">www.fda.gov/medical-devices/medical-devices-news-and-events/register-fdas-public-meeting-reauthorization-medical-device-user-fee-amendments-08042025</a>	8/4/2025	Yes
2	Q4	General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee <a href="http://www.fda.gov/advisory-committees/advisory-committee-calendar/updated-meeting-time-and-public-participation-information-august-13-2025-general-and-plastic-surgery">www.fda.gov/advisory-committees/advisory-committee-calendar/updated-meeting-time-and-public-participation-information-august-13-2025-general-and-plastic-surgery</a>	8/13/2025	No