Biocom California
MDUFA V

In 2002, the Medical Device User Fee and Modernization Act (MDUFMA) authorized the Center for Devices and Radiological Health (CDRH) to collect user fees from medical device manufacturers. In exchange, FDA agrees to improve the predictability, transparency, and consistency of the regulatory process. The Medical Device User Fee Agreement (MDUFA) is reauthorized every five years.

The MDUFA V total revenue amount for FY 2023 is $312 million. FDA collects three types of fees from sponsors and their respective FY 2023 base fees are as follows: (1) an application fee from the sponsors of a 513 (g) ($5,738), Premarket Approval (PMA) application ($425,000), 510(k) submission ($19,125),De Novo classification request ($127,000), 30-day notice ($6,800), and supplements (varies); (2) an annual establishment fee ($6,250); (3) a periodic reporting fee for certain class III devices ($14,875).

Legislative History:

2002: MDUFA was established through MDUFMA. It only authorized FDA to collect fees for premarket review.

2007: MDUFA II was signed into law with the FDA Amendments Act. It added two types of annual fees: establishment registration fee and product fee.

2012: MDUFA III was signed into law through the FDA Safety and Innovation Act. It changed the definition of establishments subject to a registration fee, thus increasing the number of device establishments paying the fee.

2017: MDUFA IV was signed into law through the FDA Reauthorization Act and advanced the utilization of real-world evidence and patient engagement

2022: MDUFA V was signed into law as part of the Continuing Appropriations and Ukraine Supplemental Appropriations Act. The bill reauthorized the program for 5 years until FY 2027.

Accomplishments: as of September 30, 2022

6,700+
devices regulated

Over-the-counter
hearing aids

Increased
Use of Real-World Evidence

752
Breakthrough Device Designations

56
marketing authorizations.

Shorter
review times

Highlights of MDUFA V:

Fee Increases

MDUFA V significantly increased the fee structure for CDRH. The base agreement includes $1.78 billion in user fee revenue for the 5-year cycle, with additional funding up to $1.9 billion if certain performance goals are met. FDA and industry will determine on an annual basis how best to use carryover funds to improve the device review process.

Total Time to Decision

CDRH has updated its total time to decision (TTD) goals for each submission type to:

- 180 FDA days for 90% of PMA submissions
- 90 FDA days for 510(k) products
- 150 FDA days for 70% of De Novo requests
- 10 months for 90% of BLA submissions.

If goals are met by 2027, CDRH will be eligible for additional user fee funds.

Shared FDA/Industry Goals:

- Quarterly and annual goal reports
- 112 calendar days average TTD for 510(k) submissions received in FY 2025-2027
- 285 calendar days average TTD for Original PMA and Panel Track Supplement submissions received in FY 2025-2027
- 90% of Pre-Submissions (up to 4300 submissions) in the MDUFA Cohort have received feedback in FY 2025-2027
- 95% of all FY 2027 deficiencies have received deficiency letters
- 80% of requests receive a MDUFA decision within 150 days for FY 2026-2027 (from 70%) if the De Novo FY 2023 TTD goal is met
- 90% of requests receive a MDUFA decision within 150 days in FY 2027 (from 70%) if the De Novo FY 2024 TTD goal is met,

Total Product Life Cycle Advisory Program (TAP)

This voluntary pilot intends to improve submission quality and efficiency of the premarket review process by providing more timely premarket interactions with FDA, improving earlier risk identification, assessment, and mitigation, and better aligning evidence generation expectations. It also aims to facilitate early interactions between FDA review teams, sponsors, and other stakeholders, such as patients, providers, and payers. The program will select 15 products in the first year, adding 100 each year until FY 2027.

Digital Health

CDRH will develop its digital health expertise, streamline FDA review processes for Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD), including exploring premarket pathways. CDRH will establish a central digital health unit within the Office of the Director to enable and harmonize approaches for products that effectively utilize Artificial Intelligence/Machine Learning/Virtual Reality/wearables. CDRH will also finalize guidance on Premarket Submissions for Device Software Functions and 510(k) submissions for software modification and promote public engagement.

Highlights of MDUFA V:

Real-World Evidence (RWE)

CDRH will continue to support the National Evaluation System for health Technology (NEST) by providing funding for the NEST Coordinating Center and hiring FDA staff with expertise in the use of RWE. The Center will continue to develop Real-World Data (RWD) and RWE policies to expand indications for use, advance clearance/approval of new devices, and clarify related reporting requirements. FDA will update the guidance Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices and advance internal training to help reach this goal.

International Harmonization

CDRH will expand its engagement with international regulators, including creating an information-sharing mechanism for international regulatory coordination and assessing implementation of International Medical Device Regulators Forum (IMDRF) technical documents. FDA will hold public meetings and create opportunities for stakeholder engagement.

Consensus Standards

FDA will use lessons learned from implementing the voluntary Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program during MDUFA IV to transition to a permanent program. ASCA aims to enhance reviewers' and manufacturers' confidence in medical device testing completed by ASCA-accredited testing laboratories. ASCA also incorporates existing international conformity assessment standards and practices where practical. The goal is to decrease the need for FDA to request additional information regarding testing methodologies for premarket submissions that include ASCA testing.

Hiring

CDRH plans to hire 210 new staff by FY 2025. FDA may add an additional 83 staff in FY 2025 conditional to meeting performance goals.

Fiscal Year:	CDRH
2023	144
2024	42
2025	24 (83)
2026	Dependent on performance improvement adjustments and if the hiring goal was increased in the prior year.
2027	
Total:	**210**

Timeline Highlights:

Starting January 1, 2023

- The TAP Pilot Program launches, with up to 15 breakthrough devices in the Office of Health Technology (OHT): Office of Cardiovascular Devices (OHT2).

Starting October 1, 2023

- FDA publishes an annual assessment of the international harmonization activities described in the strategic plan for achieving international harmonization.

Starting December 31, 2023

- FDA starts annual reporting on the ASCA program's progress.

Starting March 31, 2025

- FDA receives data to support making fee revenue adjustments to MDUFA based on its FY2023 performance.

Starting March 31, 2026

- FDA receives data to support making fee revenue adjustments to MDUFA based on its FY2024 performance.

By September 30, 2027

FDA will have completed the following MDUFA V commitments:

ASCA Program:
Creation of the ASCA program along with annual reports

TAP Program:
Up to 325 total products enrolled through FY 2027

RWE:
Updated guidance and at least two public meetings

Digital Health:
Final guidance on how to evaluate a predetermined change control plan for digital health devices.

Harmonization:
Draft strategic plan for achieving international harmonization objectives and annual assessment of the international harmonization activities described in the strategic plan.

SOURCES:

https://www.fda.gov/media/158308/download
https://www.federalregister.gov/documents/2022/10/07/2022-21967/medical-device-user-fee-rates-for-fiscal-year-2023