

MDUFA Performance Dashboards User Guide

Navigation and Relevant Information

The [MDUFA Performance Dashboards](#) are organized into three categories: 1) Medical Device Applications and Supplements; 2) Clinical Laboratory Improvement Amendments; and 3) Biologics License Application. Each category includes a Current and Historical Performance Dashboard with a navigation menu and icons at the top of each dashboard. The menu and icons include information to:

1. MDUFA Current Performance Dashboards for each category showing the two most recent years of performance for each goal
2. MDUFA Historical Performance Dashboards for each category showing the historical performance for each goal
3. MDUFA Goals Summary for each category showing the submission types, goal timelines and performance goals for MDUFA V
4. FDA-TRACK Medical Devices Home Page
5. FDA-TRACK Biologics Home Page
6. MDUFA Performance Dashboards User Guide
7. FDA-TRACK Home Page
8. Relevant Links about MDUFA
9. General background about MDUFA

FDA-TRACK: Medical Device User Fee Amendments (MDUFA) Performance Dashboards

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	Medical Device Applications and Supplements	Clinical Laboratory Improvement Amendments	Biologics License Applications
1.	• Current Performance	• Current Performance	• Current Performance
2.	• Historical Performance	• Historical Performance	• Historical Performance
3.	• Goals Summary	• Goals Summary	• Goals Summary

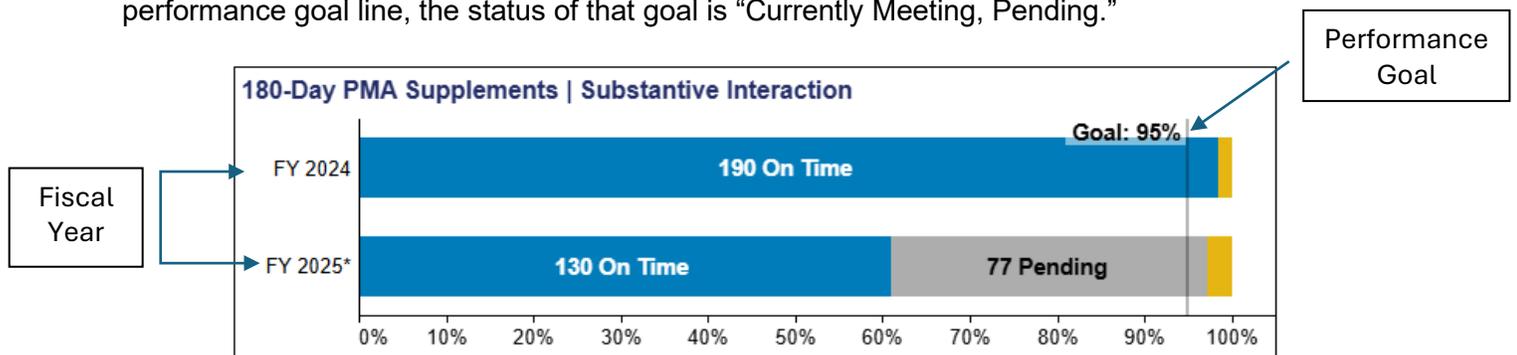
Current Performance

The Current Performance page of the MDUFA Performance Dashboards shows the two most recent years of performance for each goal. When more than one year of data is reported, the first year's data is final or updated due to review timelines that can extend beyond the fiscal year, and the second year's data is preliminary with actions still pending.

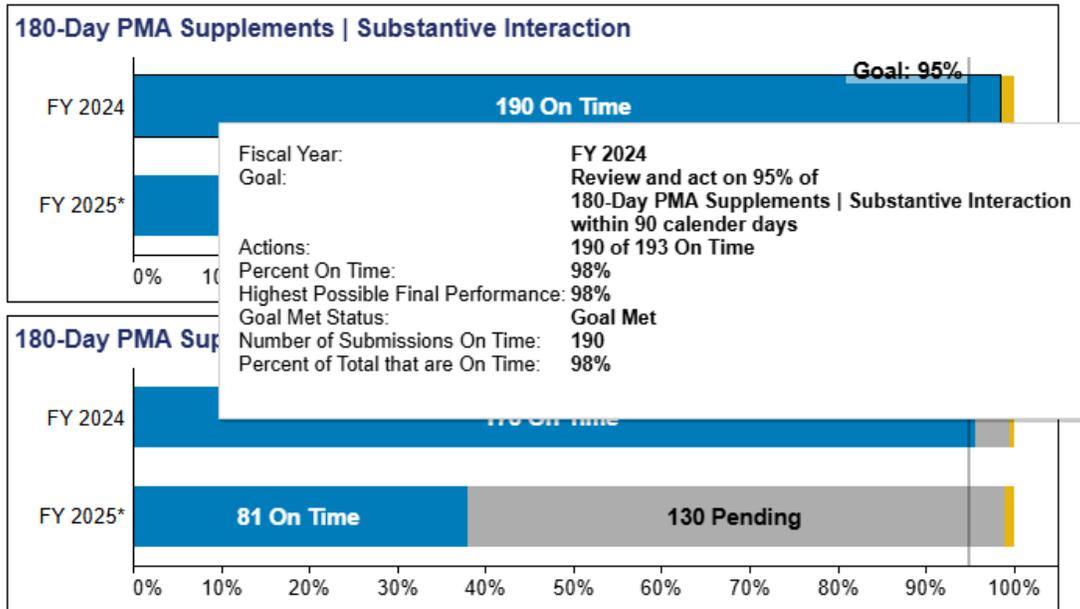
The Current Performance page displays a stacked bar chart for each year of performance:

- The color of each segment of the bar represents status:
 - Blue represents actions completed “On Time,” or within goal;
 - Gray represents actions “Pending,” or within goal and where no action has been taken;
 - Yellow represents actions “Overdue,” where action was taken after the goal date, or no action was taken and is past the goal date.
- Each bar is labeled with the number of actions in that status, except in cases where the volume of actions with that status is extremely small. In some instances, the label for the review status will not display in the graph due to space. This is an automatic default setting in the visualization software. If you hover the cursor over the section of the graph where the label is missing, the label details will appear in the Tooltip.
- The “Performance Goal” is shown as a solid vertical line on the graph:
 - If the blue bar reaches the performance goal line from the left, the goal status is “Goal Met.”
 - If the gray bar crosses the performance goal line and the Percent On Time meets or exceeds the performance goal, the goal status is “Currently Meeting, Pending.”
 - If the yellow bar reaches the performance goal line from the right, the goal status is “Goal Not Met.”
 - For certain submission types, the goal status is “Insufficient to calculate performance” if the MDUFA cohort for a given fiscal year has <10 combined submissions. Therefore, per the MDUFA V commitment letter, performance will be calculated in a future fiscal year when a combined cohort of 10 or more submissions is achieved.

In the example below, 193 submissions were filed in FY 2024. Of those submissions, 98% (190) met the performance goal, while 2% (3) did not. Since the orange bar does not reach the performance goal line from the left, the status of that goal is “Goal Met.” In FY 2025, 213 submissions were filed; 61% (130) were on time, 36% (77) were still pending, and 3% (6) were overdue. Since the gray bar reaches the performance goal line but the blue bar is below the performance goal line, the status of that goal is “Currently Meeting, Pending.”



To see a “Tooltip” that displays additional information, hover the cursor over each status on a bar, as shown in the example below.



The Tooltip provides several useful pieces of information. These include:

- Fiscal Year: The Fiscal Year of the receipt of the submission subject to the goal.
- Goal: The performance goal, type of action, and review time of the goal.
- Actions:
 - For final and updated data, the number of actions that were on time out of the total.
 - For preliminary data, the number of actions that are completed, regardless of whether they were on time or overdue, out of all potential actions.
- Percent on Time: The percent of actions that met the goal.
- Highest Possible Performance: The highest performance that can be achieved if all “Pending” within goal submissions are acted upon within goal.
- Goal Met Status: The statuses are “Goal Met,” “Currently Meeting, Pending,” “Goal Not Met,” “Insufficient to calculate performance,” or “N/A” if no submissions were filed for a goal.
- Number of Submissions: For a specified status, the number of submissions included in that status.
- Percent of Total: For a specified status, the percentage portion of submissions in relation to the total (100%).
- Additional Notes: Any additional pertinent information about how a specific performance goal is measured.

Historical Performance

The Historical Performance page of the MDUFA Performance Dashboards shows the past six years of data for each performance goal. The past five years of data are final or updated and the past year of data, is preliminary with actions still pending. The Submission Type Filter above the graphs allows for the selection of a submission type as seen in the example below.

FDA-TRACK: Medical Device User Fee Amendments Historical Performance - Medical Device Applications and Supplements

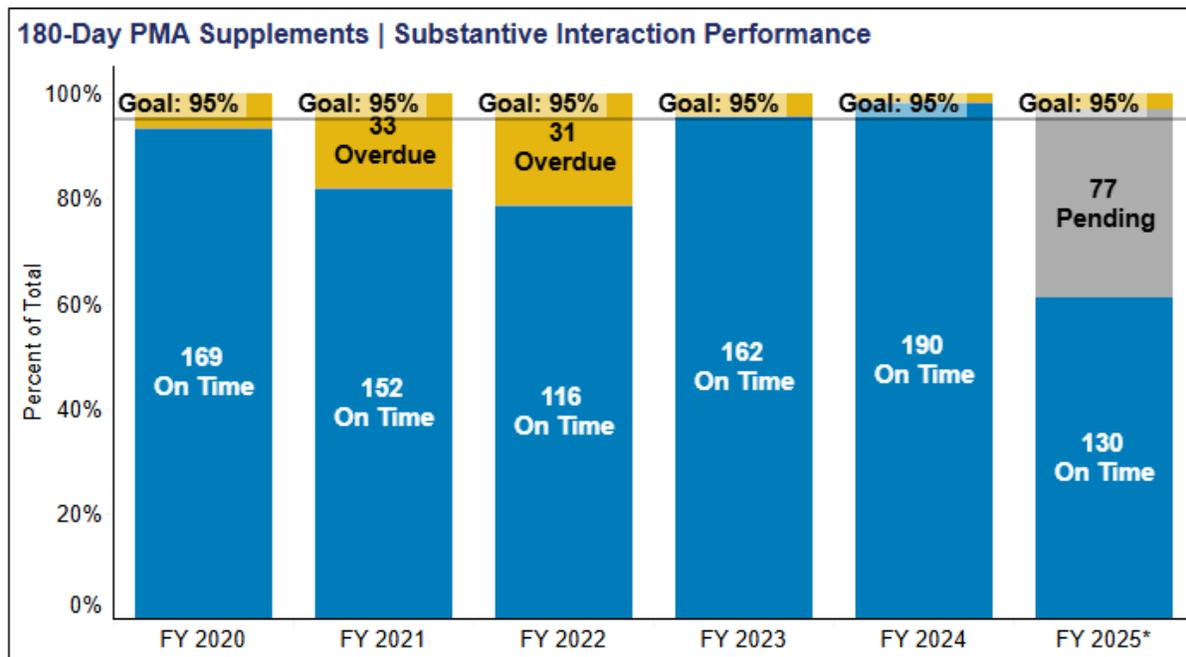
Medical Device Applications and Supplements Workload: FY 2020 to FY 2025

In the charts below, workload numbers from FY 2020 to FY 2025 are presented for medical device review goals which include: Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports; 180-Day PMA Supplements; Real-Time PMA Supplements; De Novo Classification Requests; 510(k) Premarket Notifications; and Pre-Submissions.

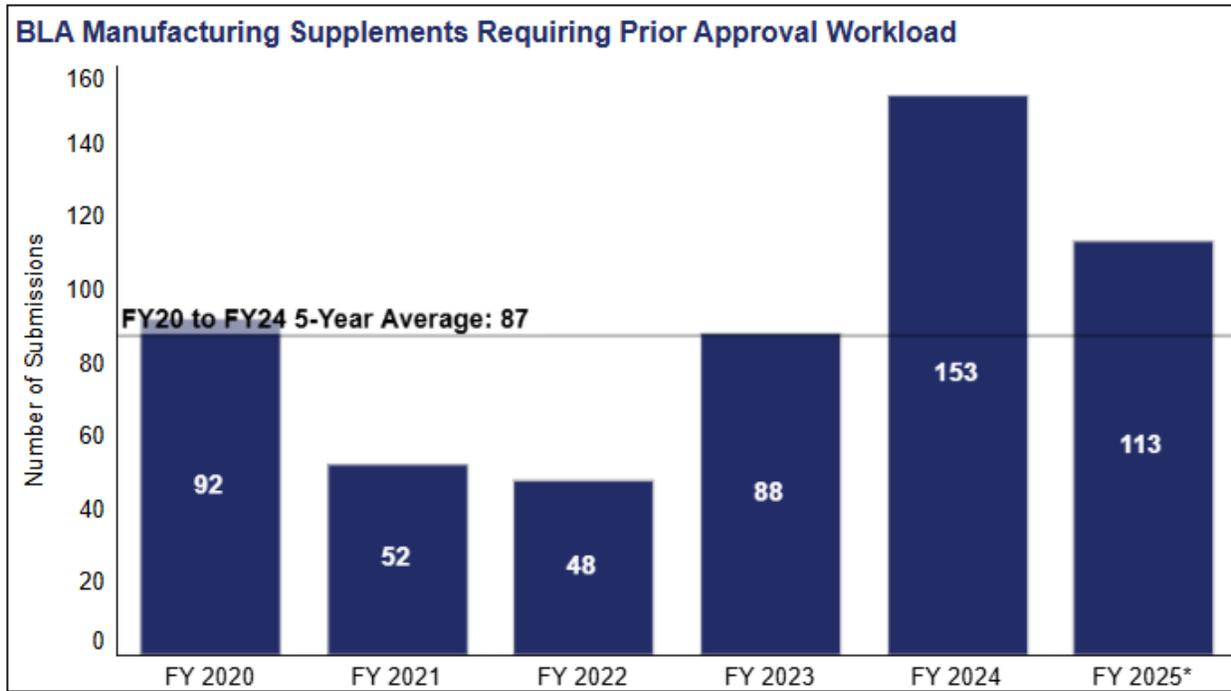
Review type definitions and other terms are found in Appendix A of the annual MDUFA Performance Report.

Submission Type: 180-Day PMA Supplements | Substantive Interaction

Review Status: On Time Pending Overdue



Workload data represents the number of submissions subject to the specific goals during the medical device review process. The “average” line through the graph represents the average number of submissions over the five-year period of final or updated performance data, excluding the preliminary data.



Datasets and Footnotes

The data in each dashboard can be downloaded by selecting the dataset button below each dashboard, as shown below for the Current Performance for the Medical Device Applications and Supplements Dashboard.

[Download Medical Device Applications and Supplements Dataset](#)

Footnotes are provided below each dashboard showing relevant information, for example, noting whether data is preliminary, or clarifying differences in data inclusion criteria for specific submission types.

Footnotes:

* Performance is currently preliminary due to pending submissions.

** Third Party 510(k)s have a Decision but do not have a Substantive Interaction. As such, Third Party and non-Third Party 510(k)s are included in the Decision data, but only non-Third Party 510(k)s are included in the Substantive Interaction data.