



FDA Update

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Summary

- Actions to Improve Pre-Market Programs
 - Triage Pilot
- Organizational Changes
- MDUFA III and FDASIA

Actions to Improve Pre-Market Programs

- Culture change toward greater transparency, interaction, collaboration, and the appropriate balancing of benefits and risks
- Assure predictable and consistent recommendations, decision making, and application of the least burdensome principle
- Implement efficient processes and use of resources

Culture Change

- Better engagement with industry
- Greater use of external experts
- Balance benefits and risks and apply a more patient-centric approach
- Smart Regulation



Predictable and Consistent Recommendations

- Management Oversight
- Enhancing Training
- Improving Internal Processes
- Transparency Through Guidances
- New Communication Tools.



Improving Internal Processes

- Establish a Center Science Council
- Standard Operating Procedures (SOP)
 - When Additional Information can be Requested
 - Change in Reviewer
 - Corrective and Preventive Actions (CAPA)
- IVD Triage Program

Triage Pilot Overview

- Internal management tool
- Traditional 510(k)
- Reduce review time of good quality 510(k)s
- Two tiers:
 - **Quick Review Tier** – good quality submissions that fit quick review criteria; clear within 30 days
 - **Regular Review Tier** - current normal 510(k) review process; clear within 90 days
- ***Pilot Duration:*** 6 months (beginning April 2, 2012)

Triage Pilot Early Metrics

Two Month Data

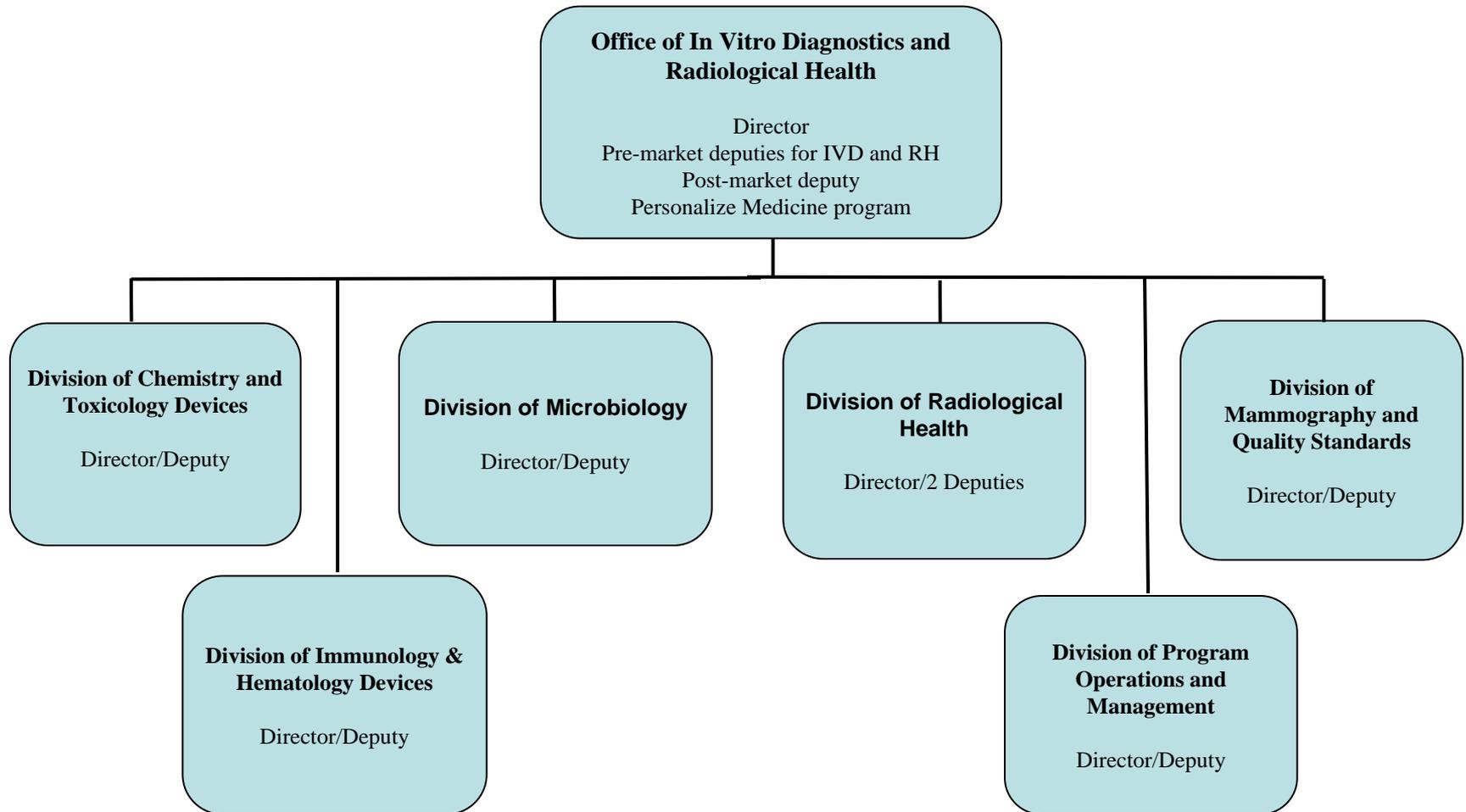
- 1st month - 15% of traditional 510(k)s entered into the program.
- 2nd month - 20% of traditional 510(k)s entered into the program.
- Average 27-28 days
- Some refusals to enter the program
- Multiple reasons why submissions are not accepted

Organizational Change – OIVD

- Working reducing manager/reviewer ratio currently 1/27 - ideal 1/10
- Adding post-market for radiology, mammography, and Radiological Health



Proposed Organizational Change

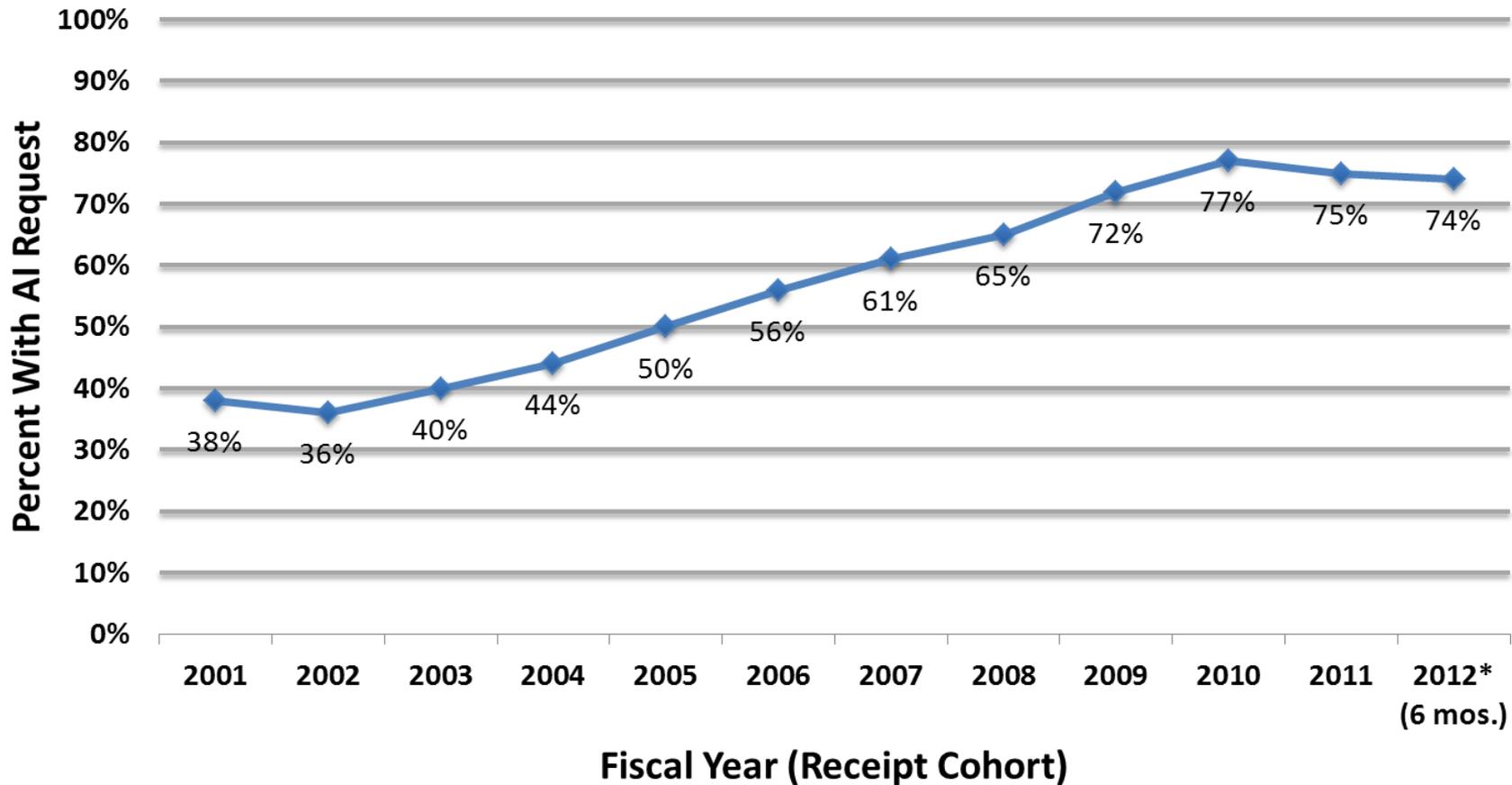




510(k)s



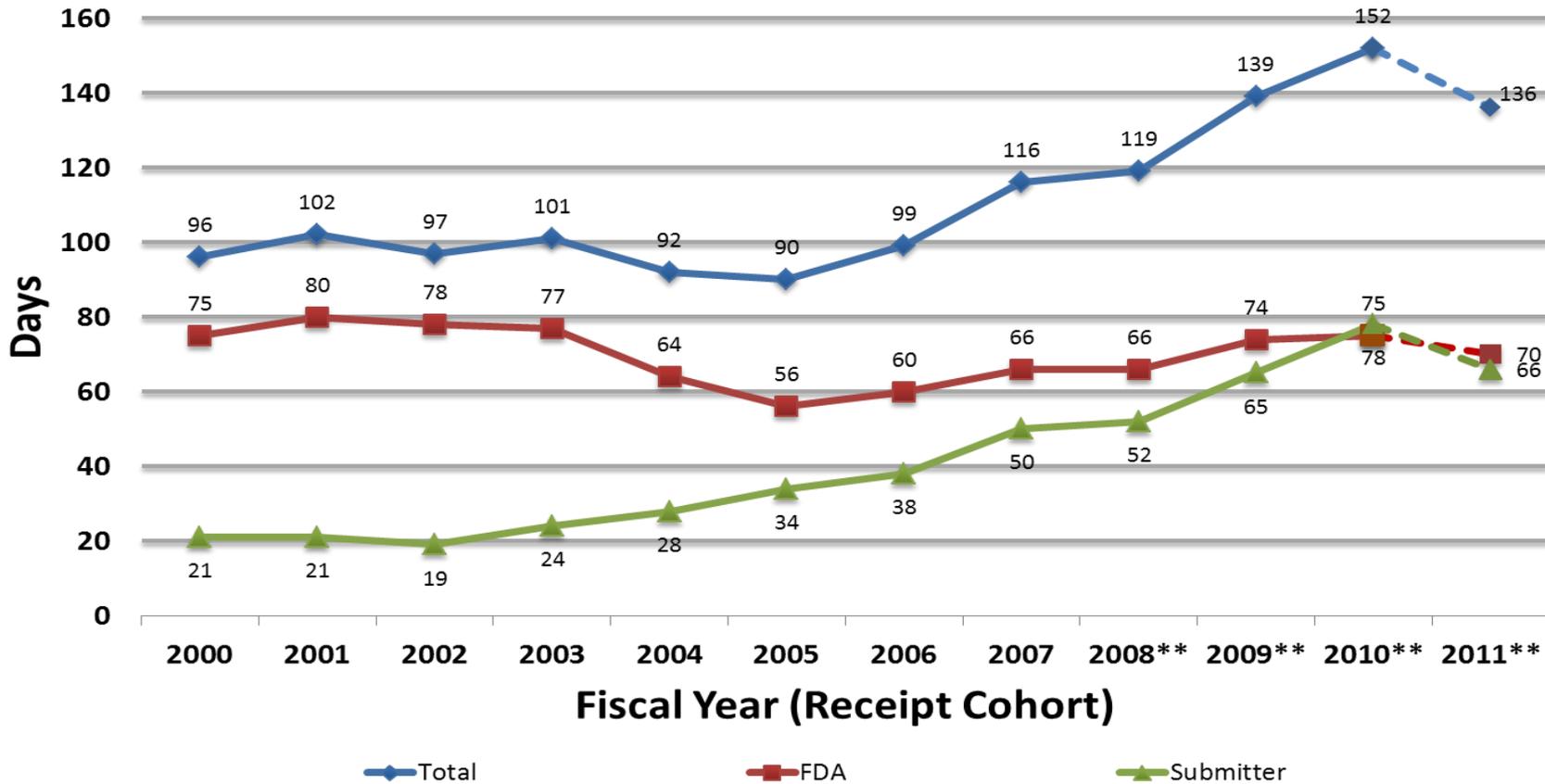
Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle





Average Time to Decision: 510(k)s*

(Receipt Cohorts as of June 30, 2012)



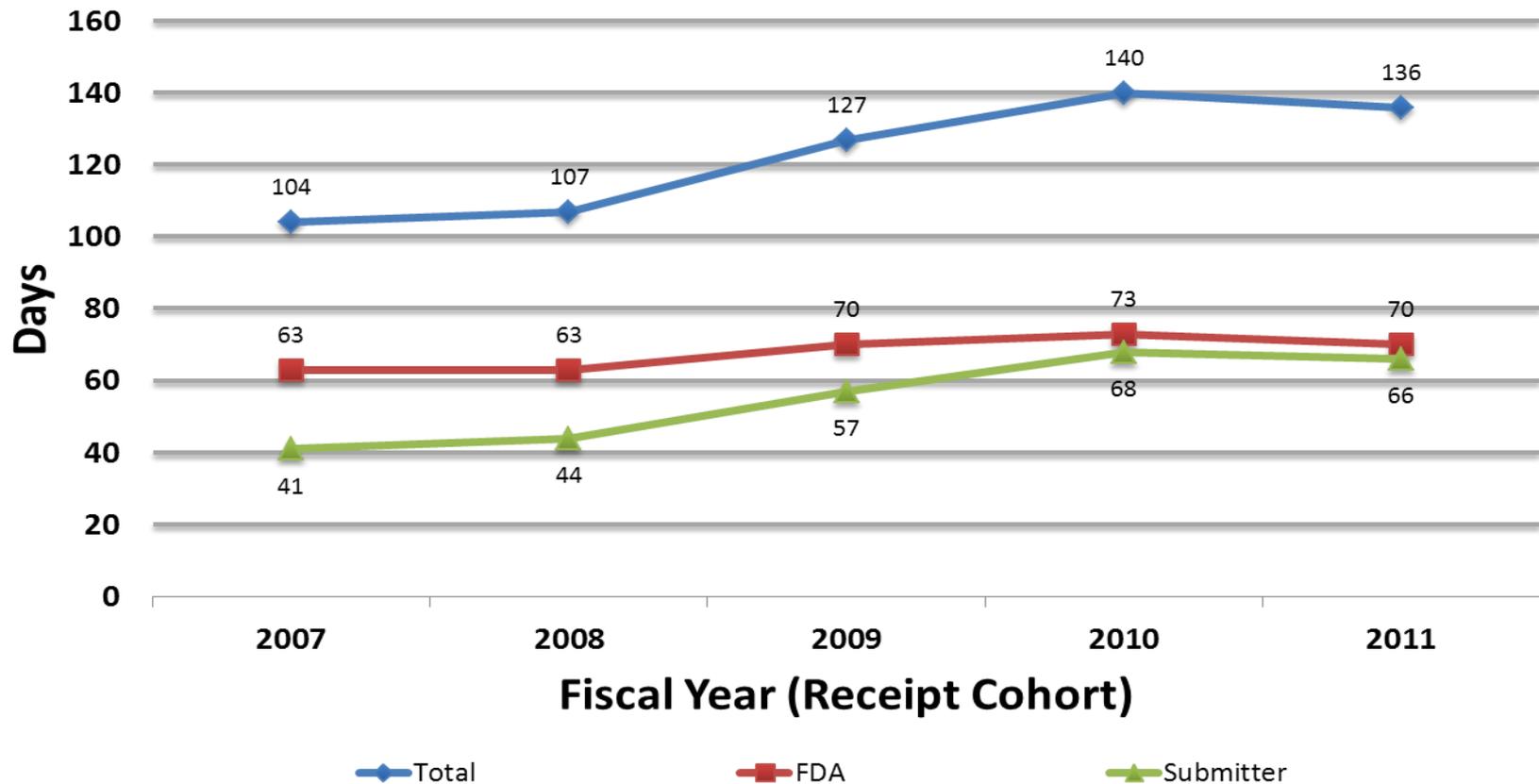
*SE and NSE decisions only; times may not add to total due to rounding

**Cohorts still open; FY 2011 cohort is only 95% closed and average times will increase



Average Time to Decision: 510(k)s*

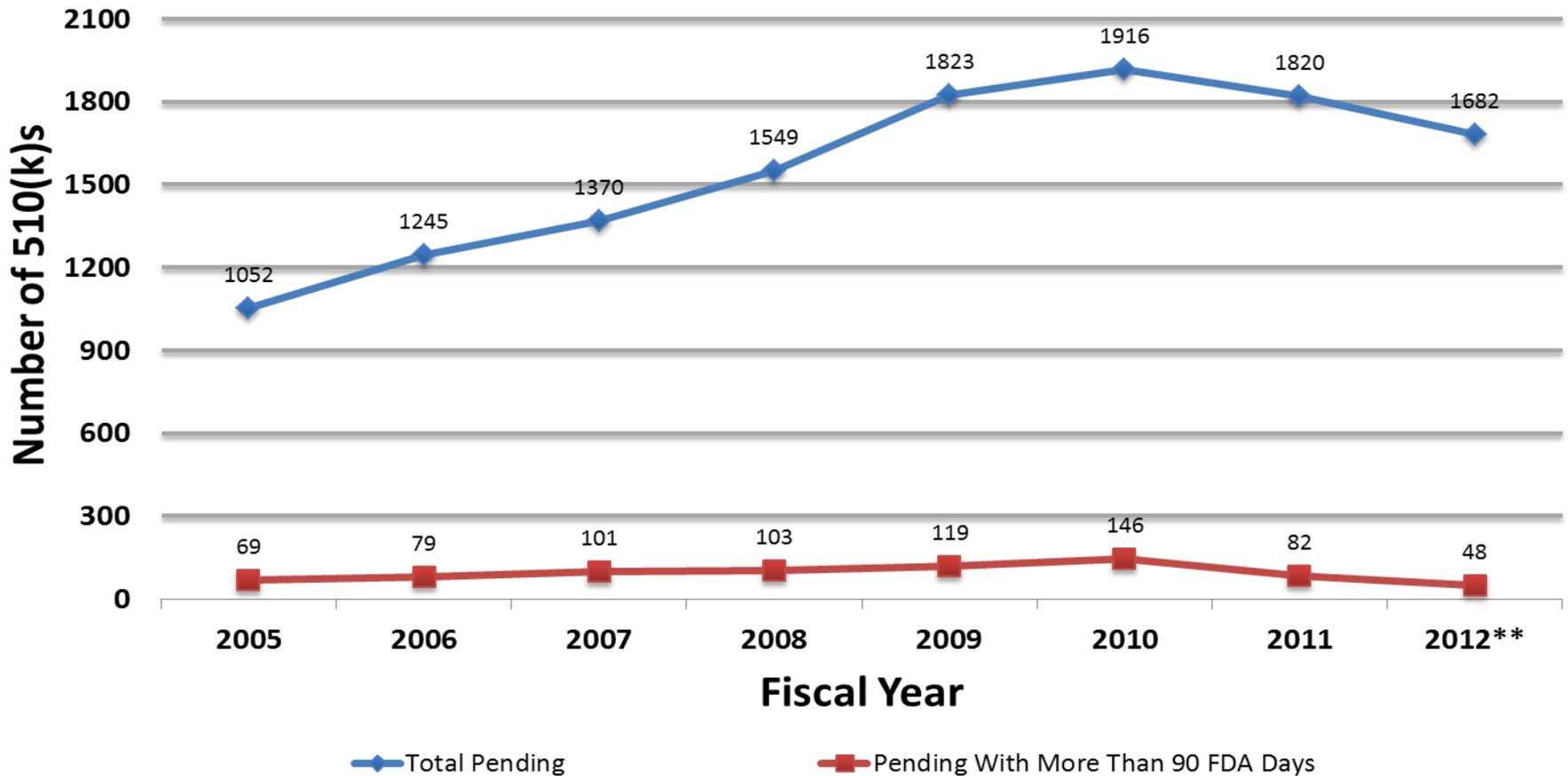
- Comparison of Receipt Cohorts When 95% Closed -



*SE and NSE decisions only; times may not add to total due to rounding



510(k)s Pending* at End of Year

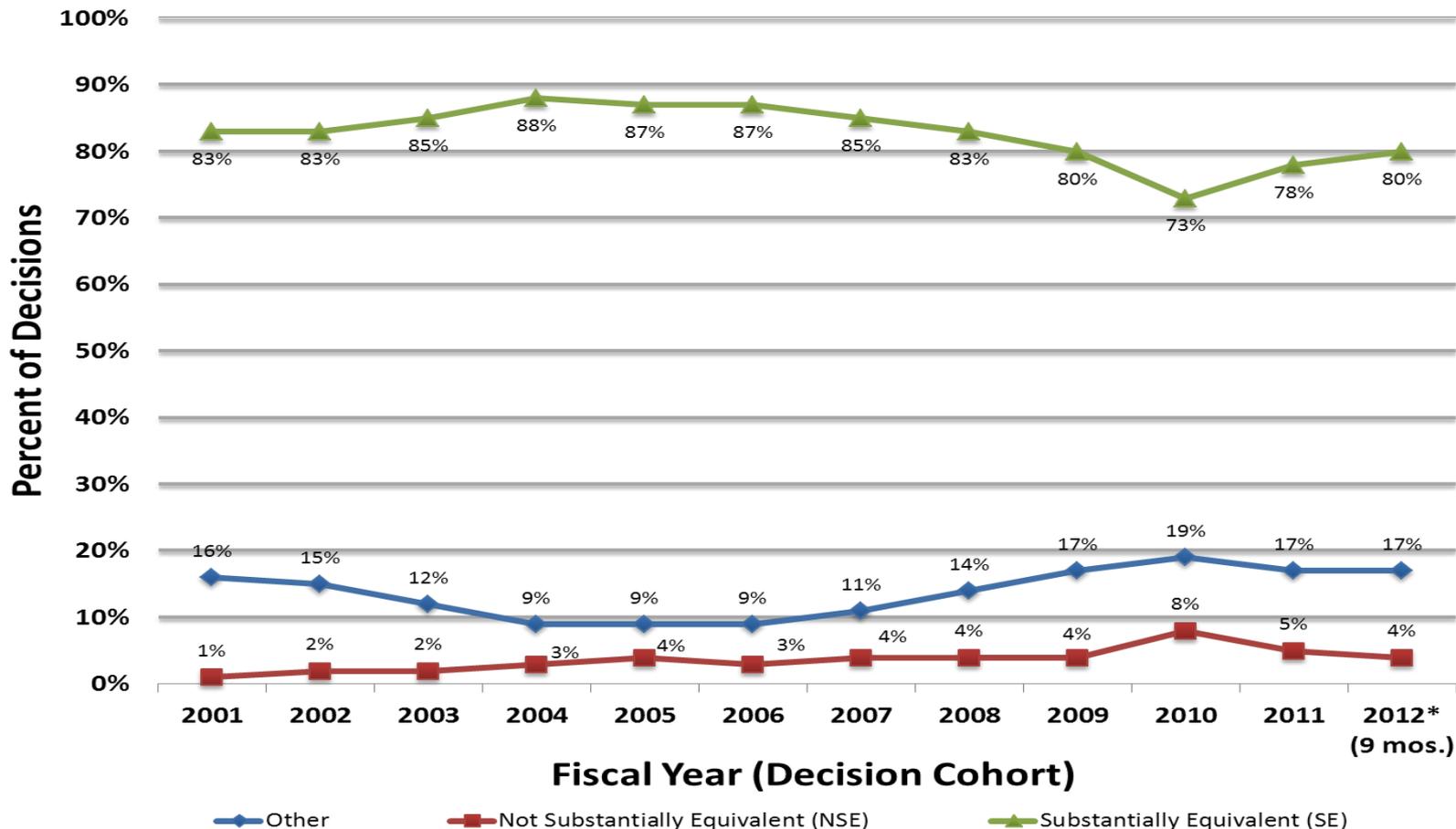


*Under review or on hold

**FY 2012 is as of June 30, 2012



Percent of 510(k)s Determined to be Substantially Equivalent (SE)

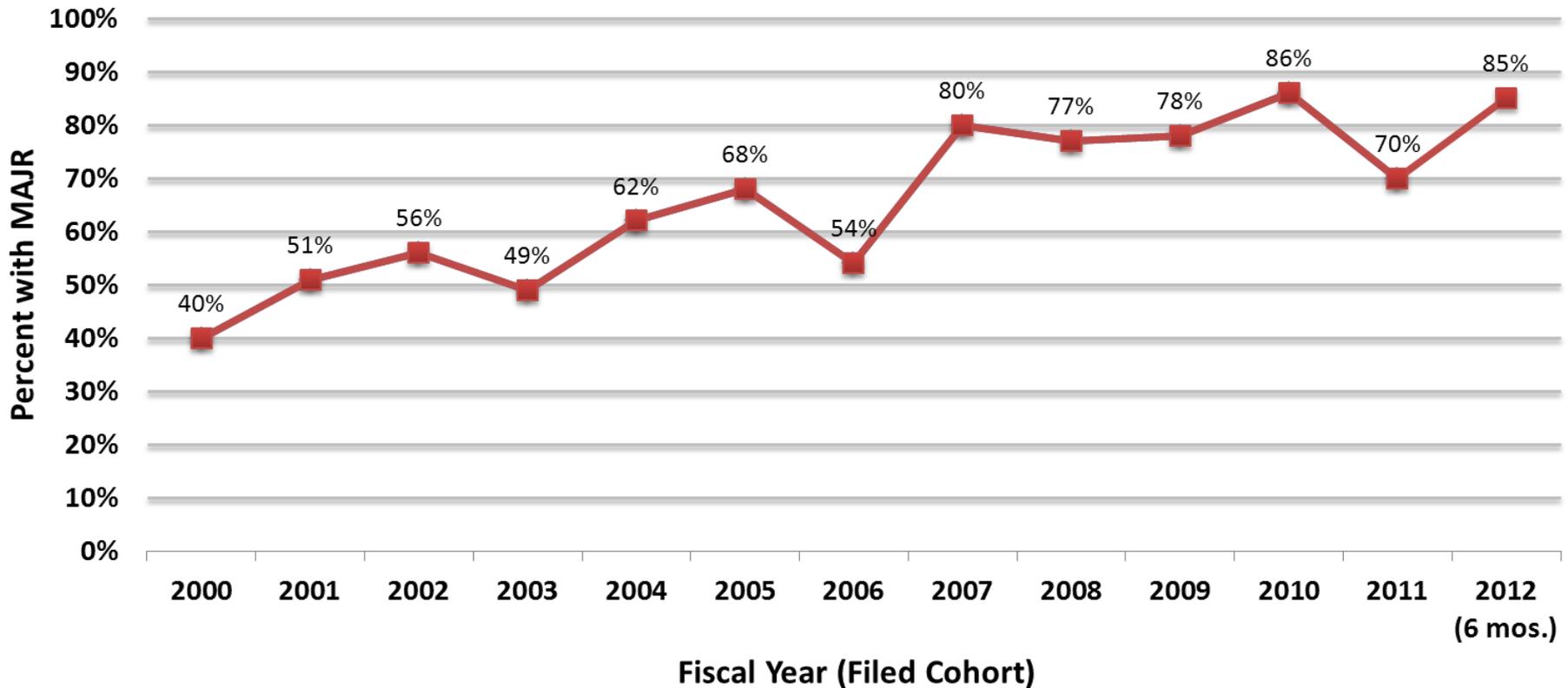




PMA_s



Percent of PMAs With Major Deficiency Letter (MAJR) on 1st FDA Review Cycle*

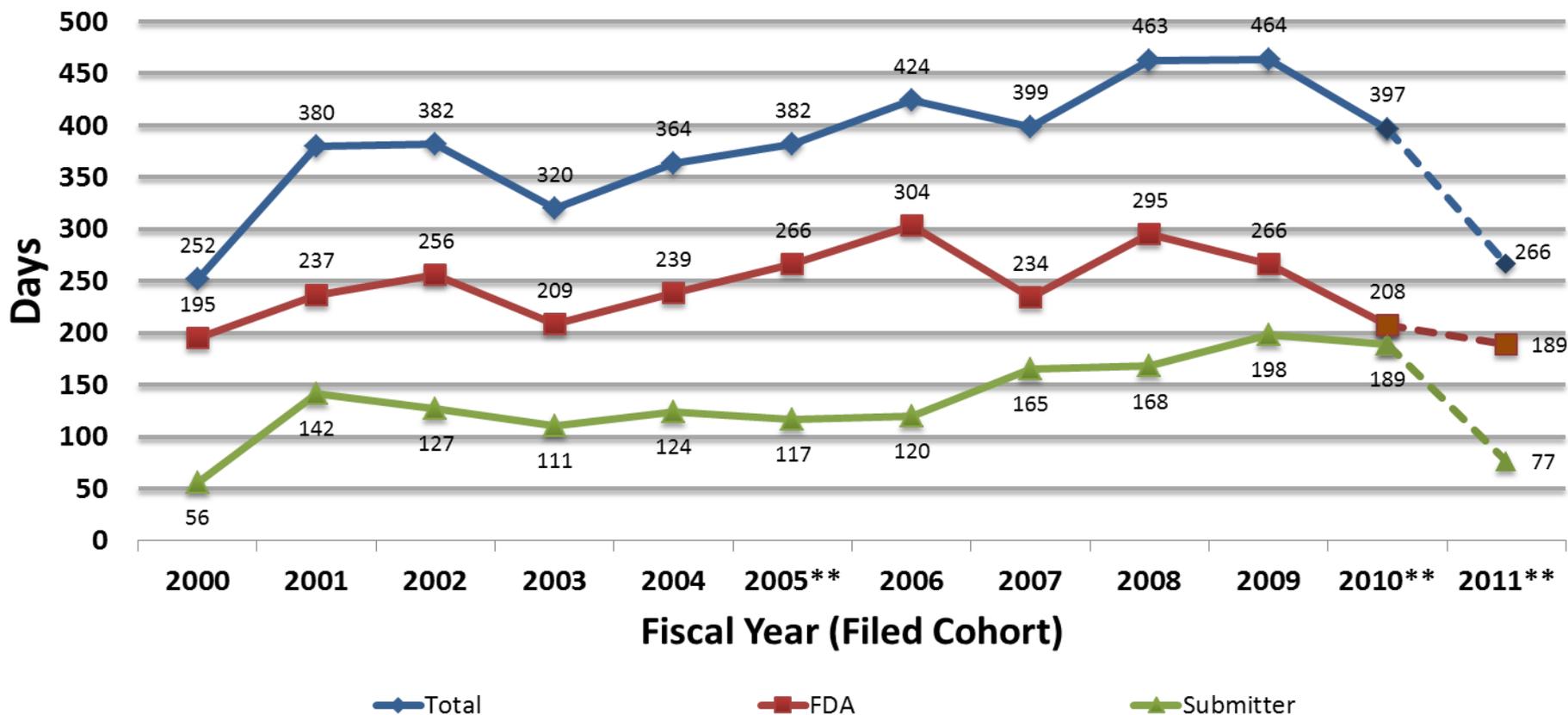


*Includes all filed original PMAs (1st cycle completed for all cohorts)



Average Time to MDUFA Decision: PMAs*

(Filed Cohorts as of July 16, 2012)



*Includes all filed original PMAs; times may not add to total due to rounding

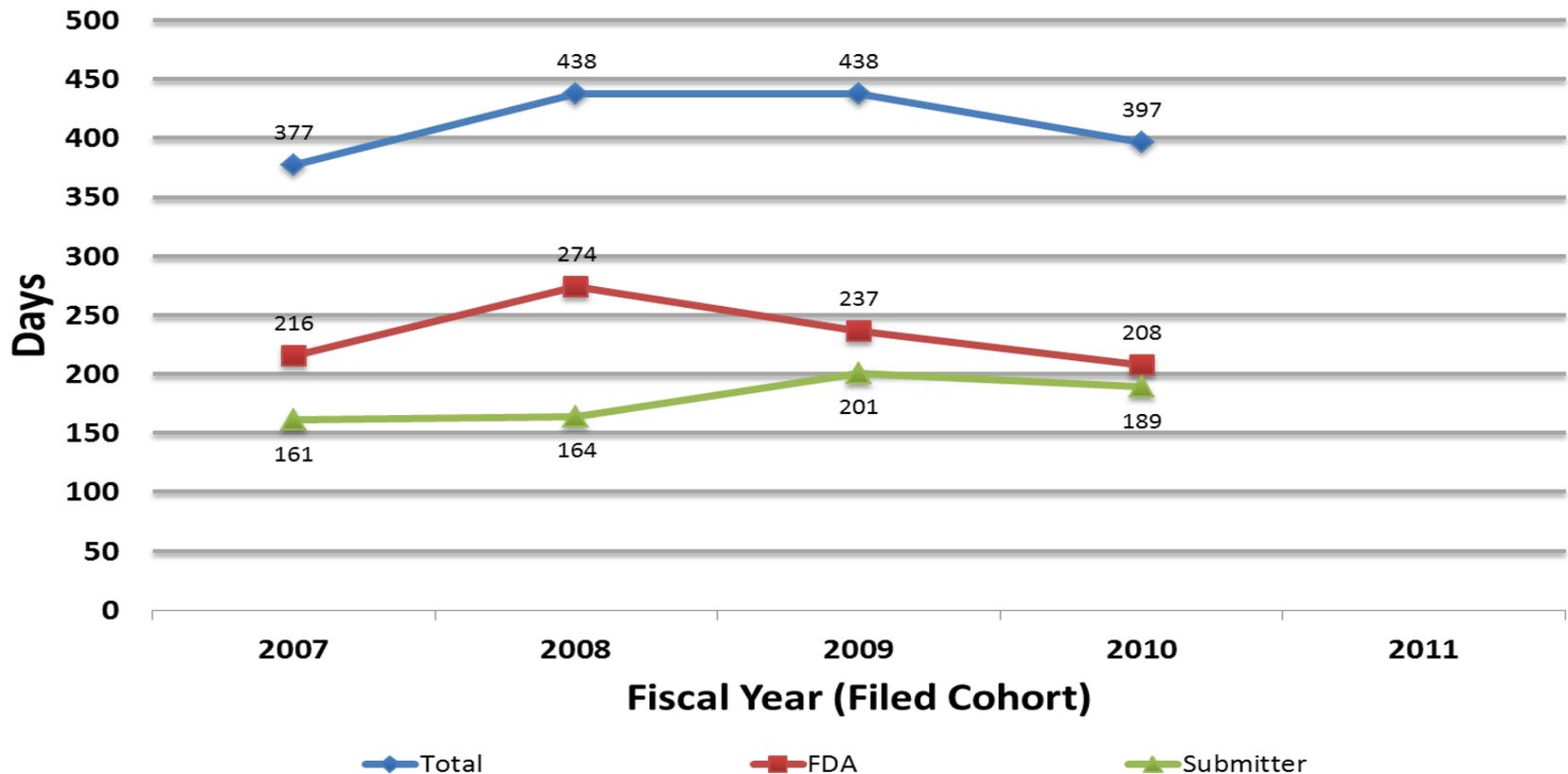
**Cohorts still open, average times will increase; percent of cohort with MDUFA decision:

FY05 = 98% (46/47); FY10 = 98% (42/43); FY11 = 81% (35/43)



Average Time to MDUFA Decision: PMAs*

- Comparison of Filed Cohorts When Approx. 98% Closed** -



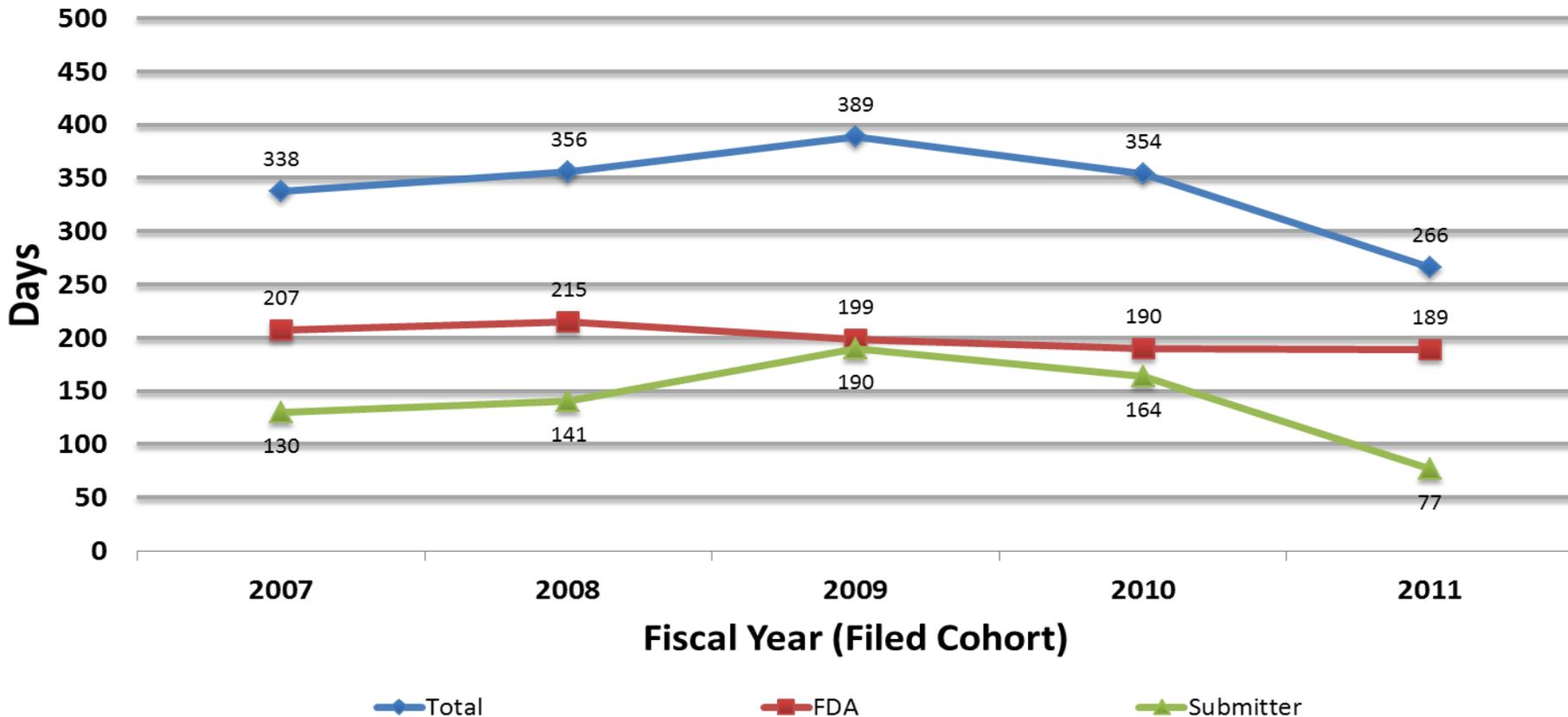
*Includes all filed original PMAs; times may not add to total due to rounding

**Proportion of cohort closed (MDUFA decision): FY07 = 34/35; FY08 = 29/30; FY09 = 31/32; FY10 = 42/43; FY11 = (not yet 98%)



Average Time to MDUFA Decision: PMAs*

- Comparison of Filed Cohorts When Approx. 81% Closed** -

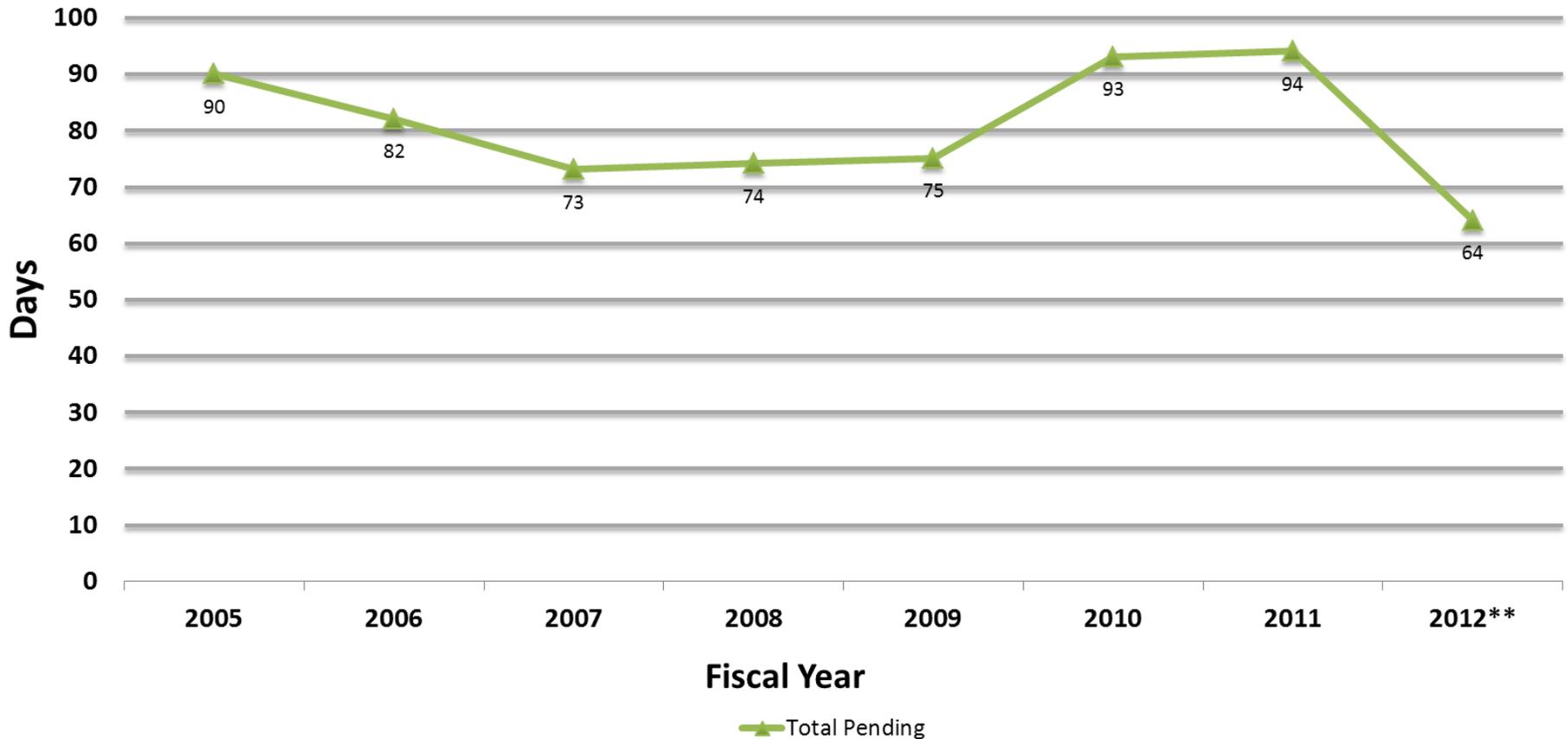


*Includes all filed original PMAs; times may not add to total due to rounding

**Proportion of cohort closed (MDUFA decision): FY07 = 28/35; FY08 = 23/30; FY09 = 26/32; FY10 = 35/43; FY11 = 35/43



PMA's Pending* at End of Year

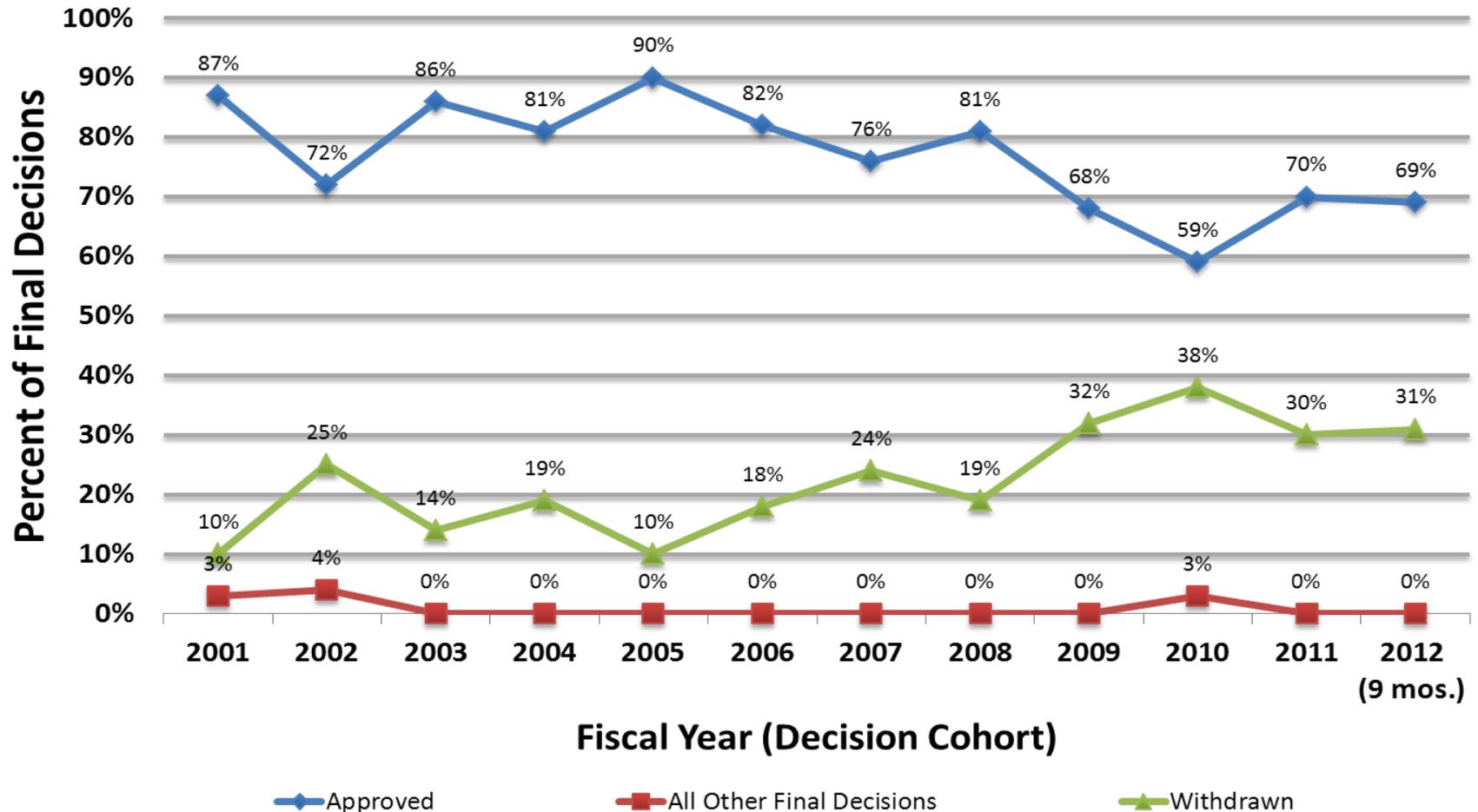


*All original PMA's under review or on hold

**FY 2012 is as of July 16, 2012



Percent of PMAs Approved*



*Based on original PMAs that were accepted for filing



FDASIA

- MDUFMA III
 - Implementation begins on October 1st
- Other Provisions
 - July 9th, On president's signature

Key Points of MDUFA III

- Additional Funding – Challenging goals
- Substantive Interaction goals
- Shared Outcome Goal – Total Time
 - More responsibility on industry
- Refuse to Accept policy
- Supports IT Infrastructure
- No Submission Left Behind



Key Points of MDUFA III

- Resources allocated to support a reorganization

- Commitment letter posted

<http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf>

Other FDASIA Provisions

- Limits IDE disapproval to safety issues
- Provides for clinical hold of IDEs
- New *de novo* pathway
- Strict timelines for appeals
- Requires withdrawal of modifications guidance and report to congress
- Program for analysis of recalls



More FDASIA Provisions

- Expands for profit HDEs
- Expands Sentinel for devices
- Sets timeline for start of 522 studies after they have been ordered
- Sets new process for reclassification
- Requires the FDA to notify congress 60 days before publishing LDT guidance.



Thanks