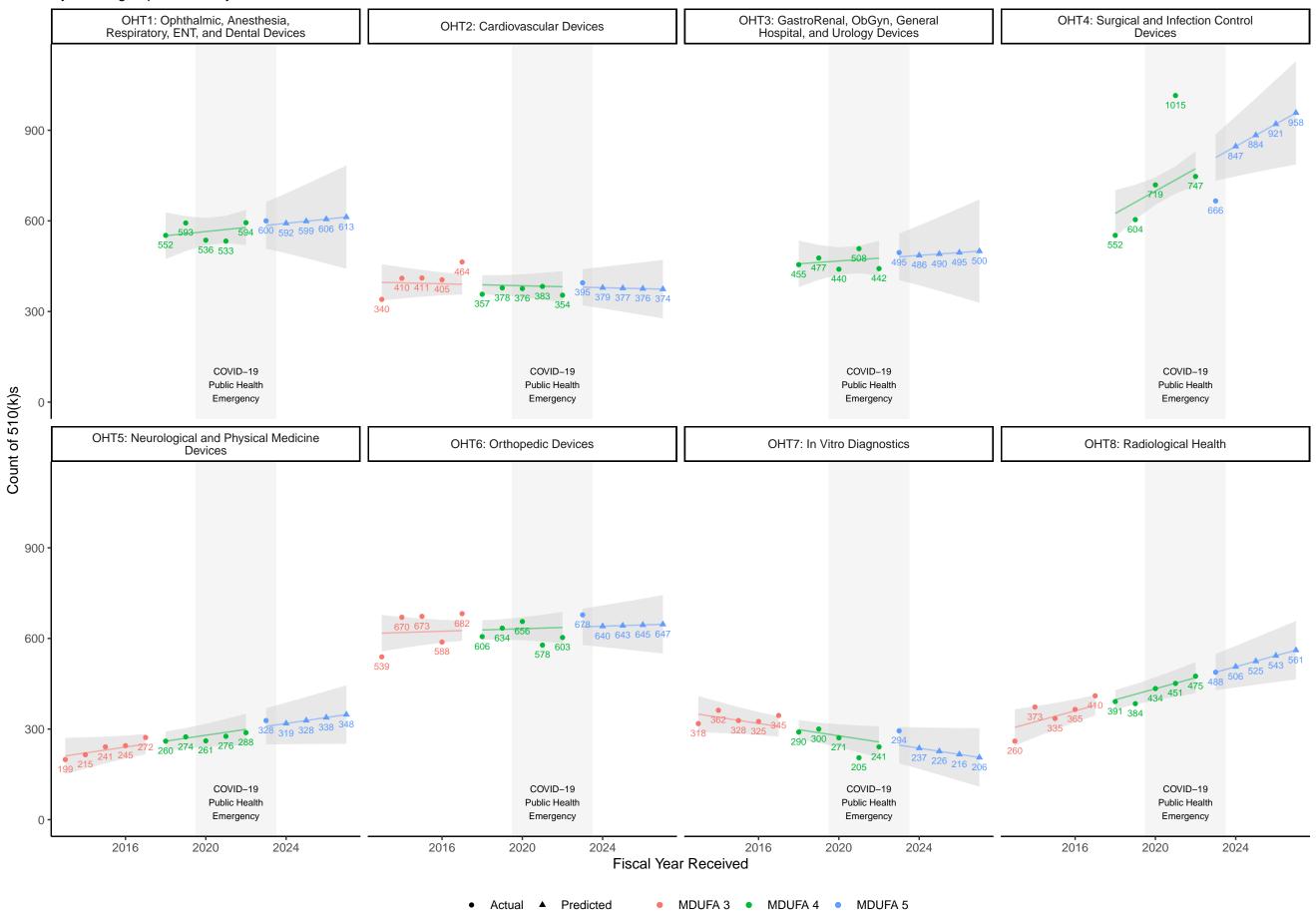
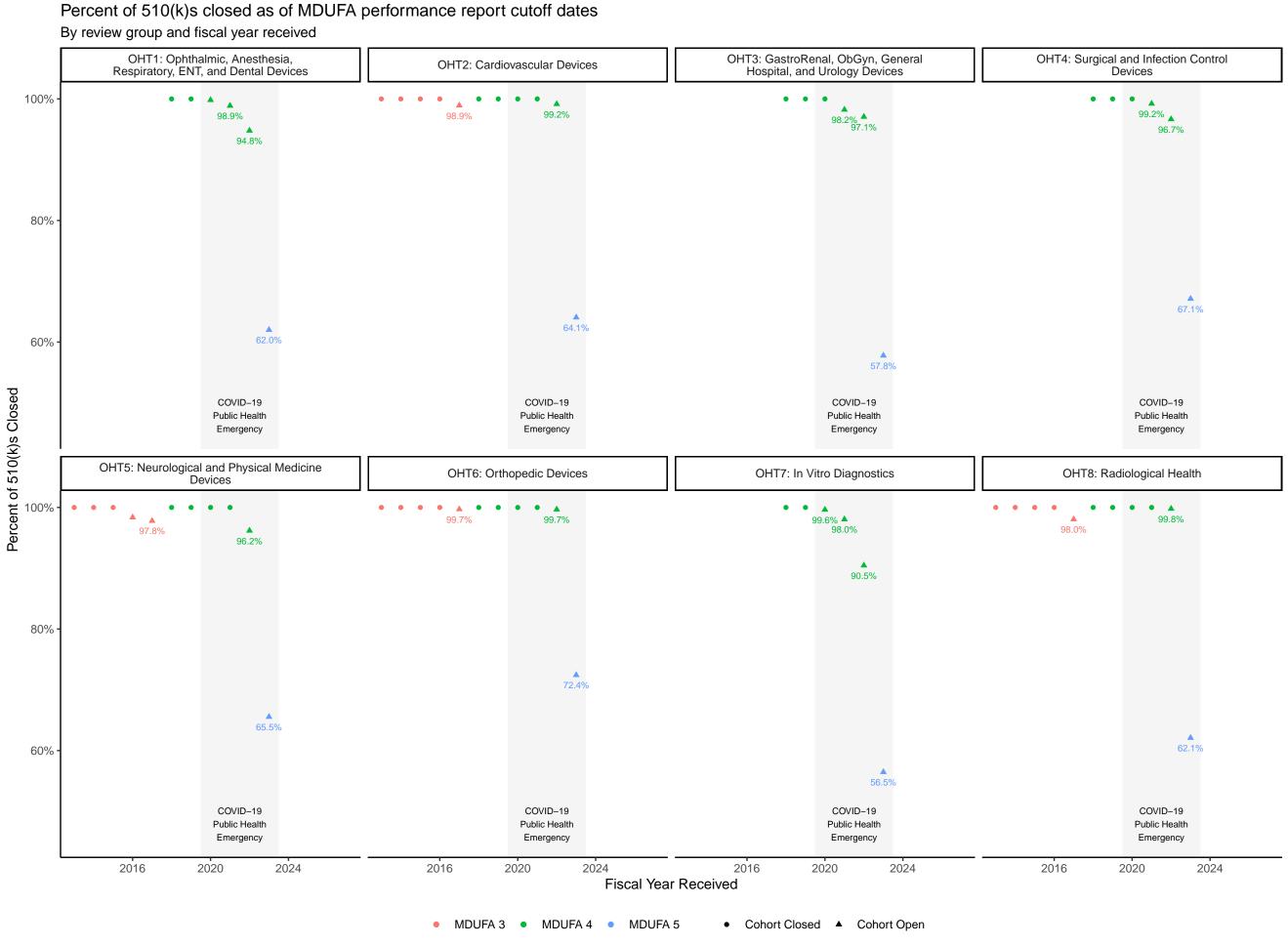
510(k)s received

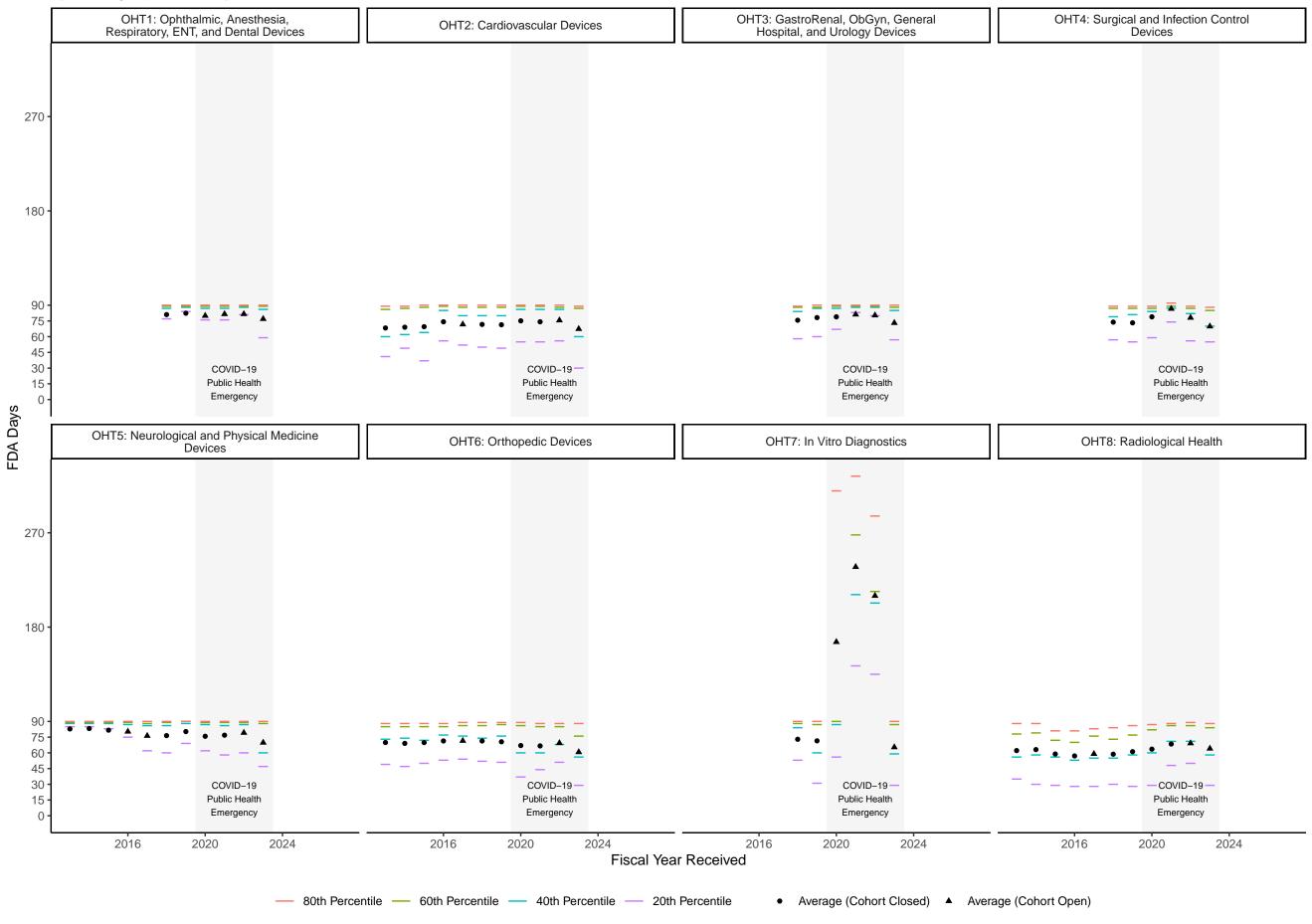
By review group and fiscal year received





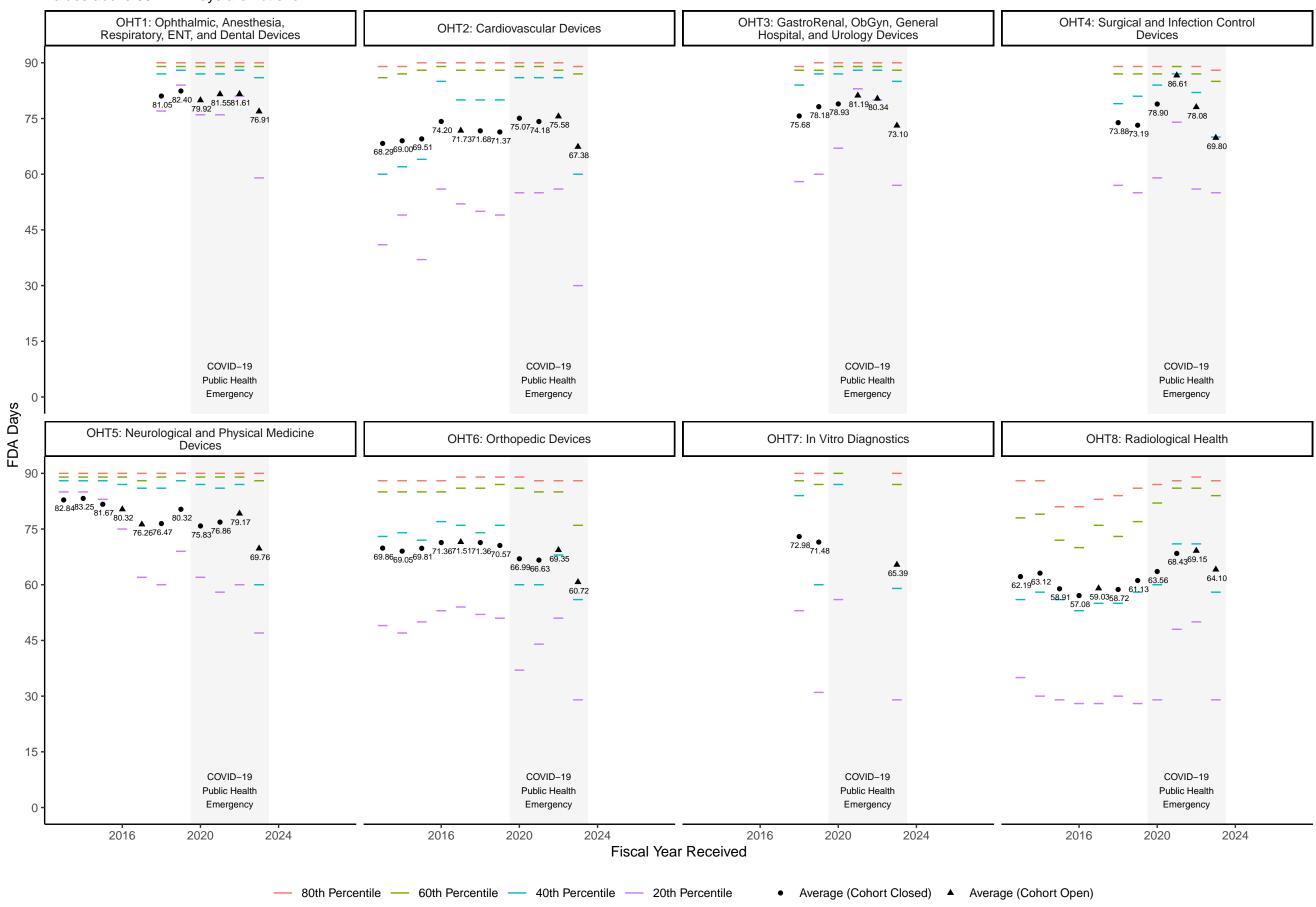
510(k) FDA Days performance metrics as of MDUFA performance report cutoff dates

By review group and fiscal year received



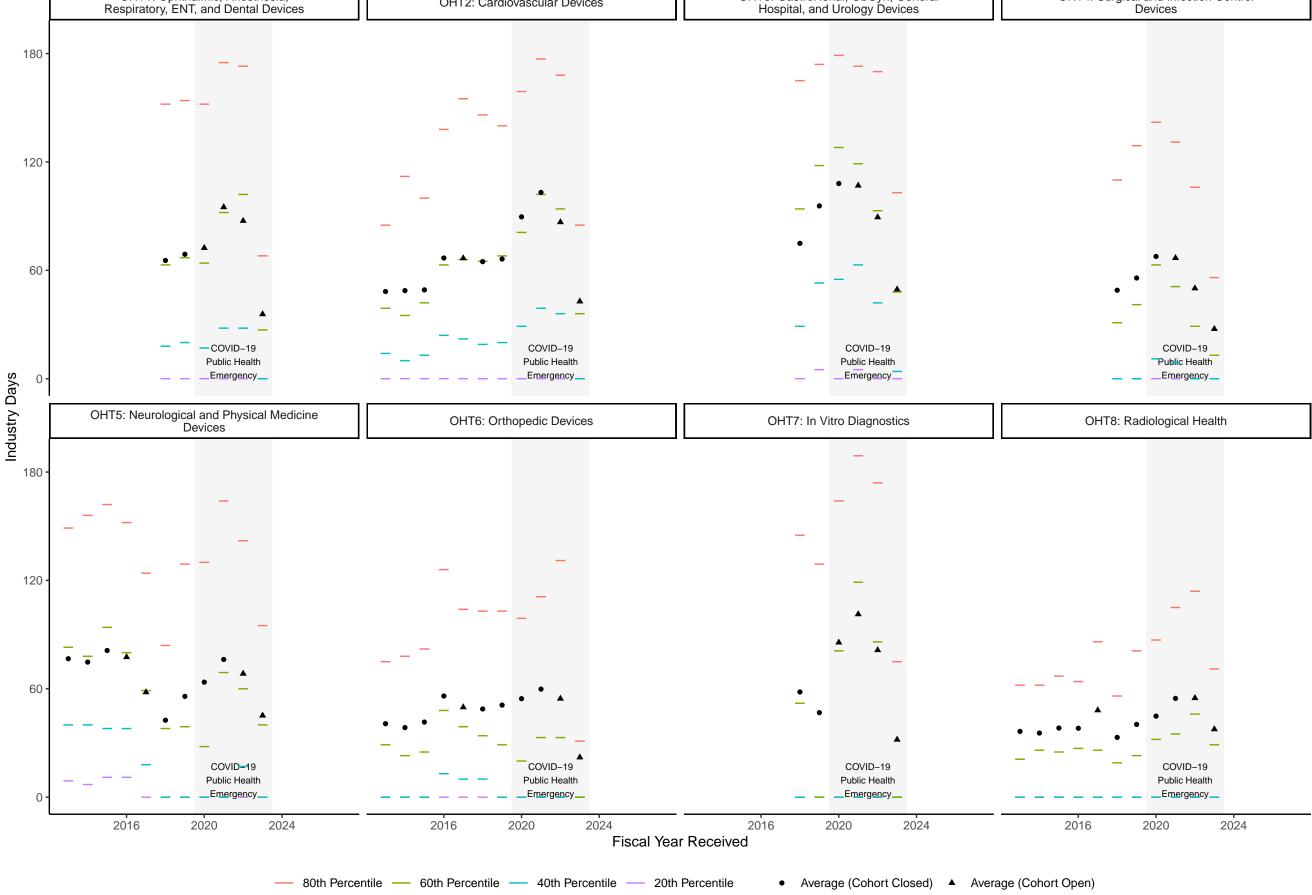
510(k) FDA Days performance metrics as of MDUFA performance report cutoff dates

By review group and fiscal year received Values above 90 FDA Days are not shown

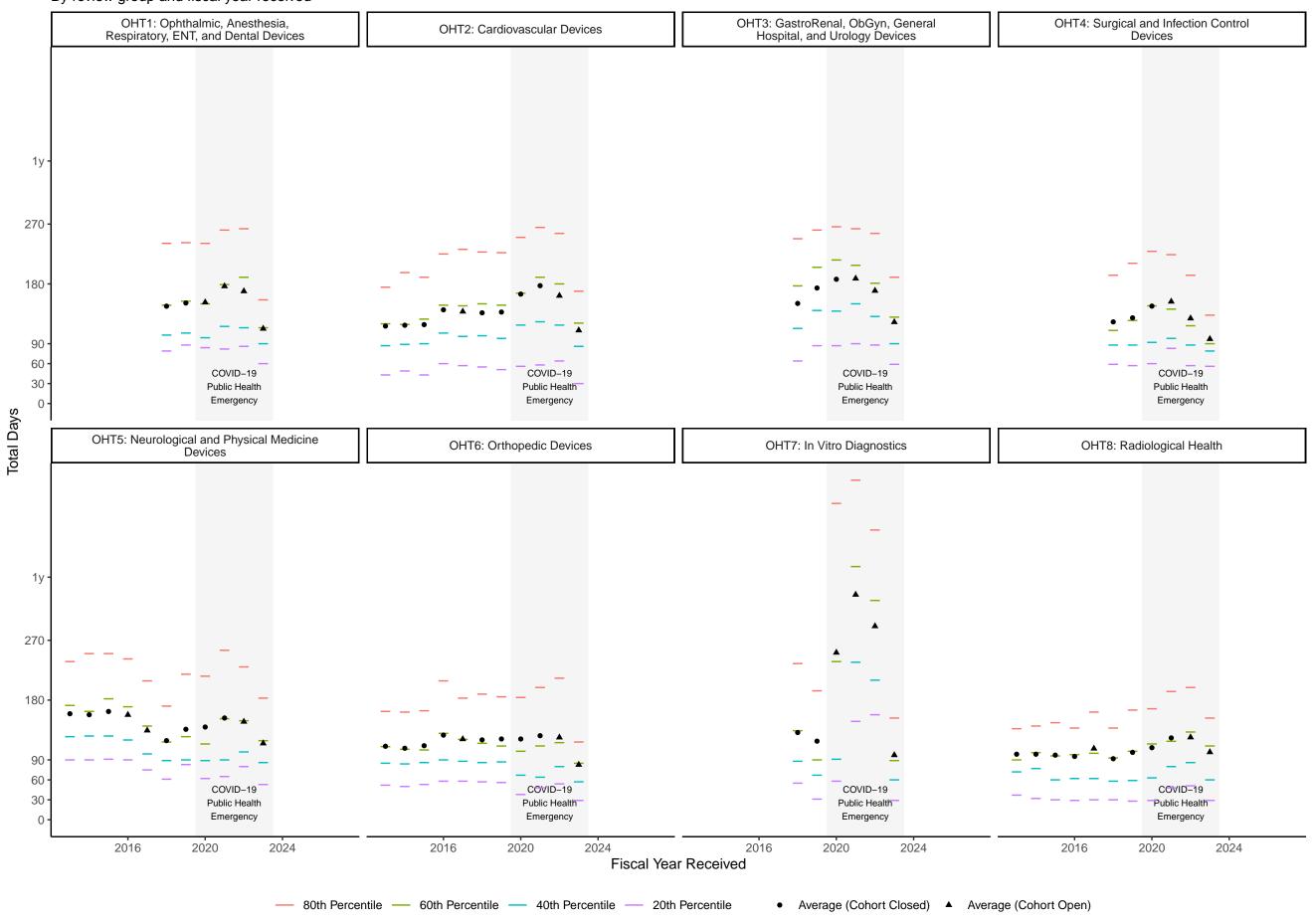


FDA Days on-time performance percentage for 510(k)s as of MDUFA performance report cutoff dates By review group and fiscal year received OHT1: Ophthalmic, Anesthesia, OHT3: GastroRenal, ObGyn, General OHT4: Surgical and Infection Control OHT2: Cardiovascular Devices Respiratory, ENT, and Dental Devices Hospital, and Urology Devices **Devices** 98.7% 96.8% 97.1% 99.3% 98.1% 96.5% 95.5% 97.0% 97.2% 96.9% 100% • • 🛦 99.0% 98.7% 97.2% 96.4% 99.4% 97.8% 100% 98.2% 99.0% 96.9% 96.8% <sup>97.8</sup>% 94.6% 90.0% 75% 75.3% 50% COVID-19 COVID-19 COVID-19 COVID-19 Public Health Public Health Public Health Public Health 510(k)s Reviewed within 90 FDA Days (%) Emergency Emergency Emergency Emergency OHT5: Neurological and Physical Medicine **OHT6: Orthopedic Devices** OHT7: In Vitro Diagnostics OHT8: Radiological Health Devices 100%  $\blacktriangle$ • 4 • • • • 4 4 100% 100% 99.1% 97.4% 98.0% 97.8% <sup>1</sup> 96.2% 99.3% 99.7% 99.7% 99.0% 98.5% 99.6% 99.8% 100% 99.8% 99.8% 100% 99.6% 98.3% 100% 60.5% 50% COVID-19 COVID-19 COVID-19 COVID-19 Public Health Public Health Public Health Public Health Emergency Emergency Emergency Emergency 25% **A A** 8.7% 8.2% 0% 2016 2020 2024 2016 2020 2024 2016 2020 2024 2016 2020 2024 Fiscal Year Received

Cohort Closed ▲ Cohort Open

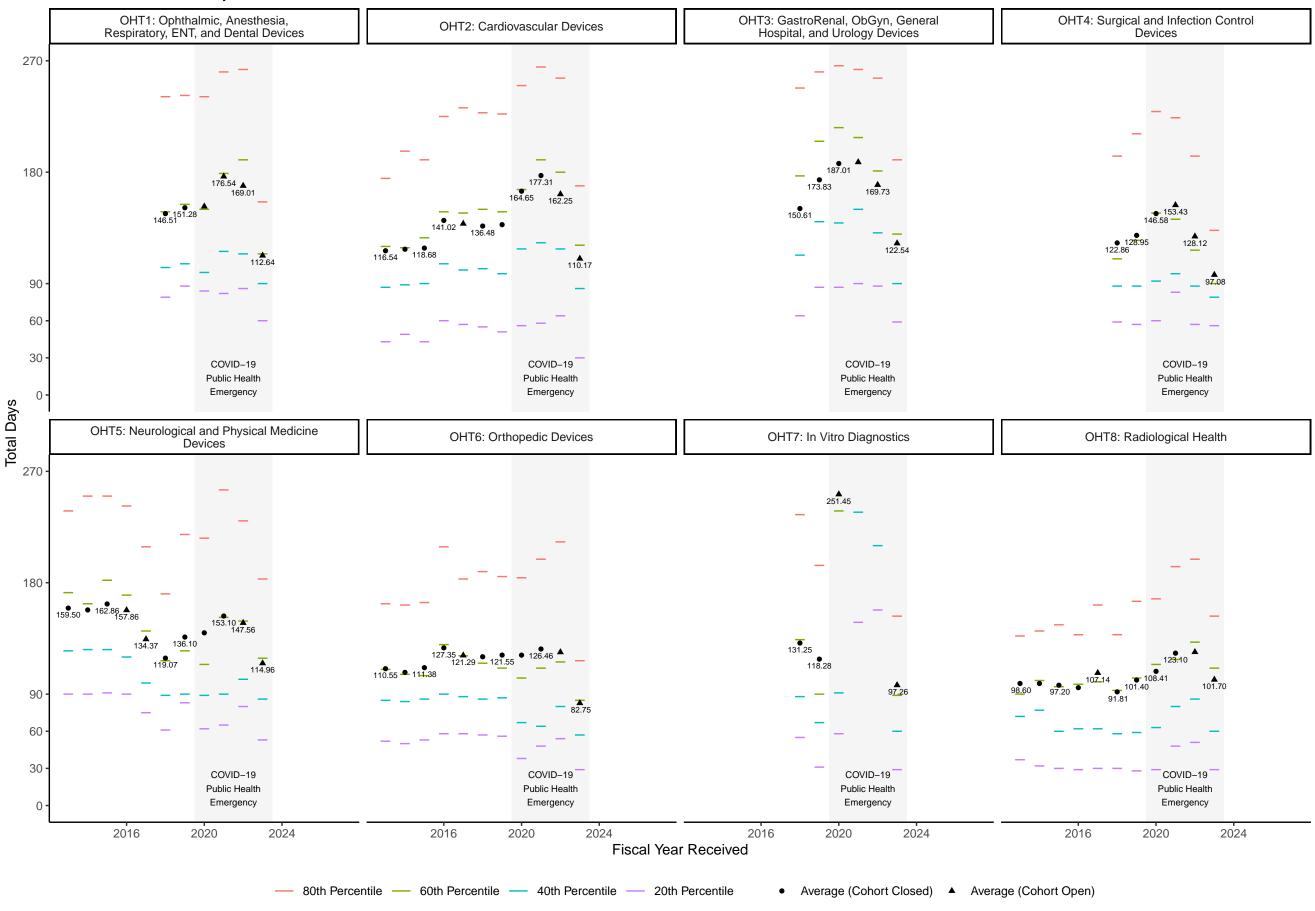


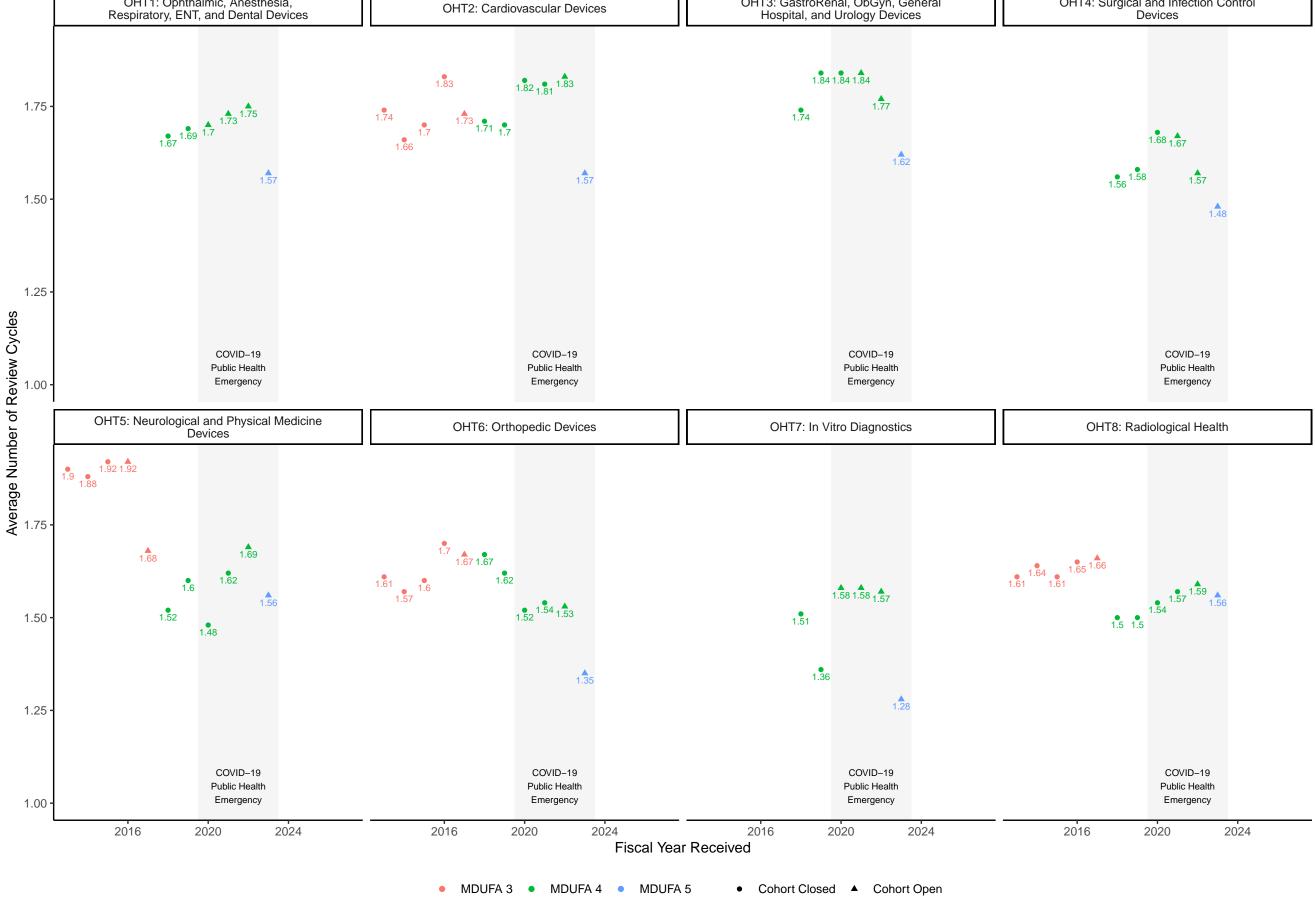
510(k) Total Days performance metrics as of MDUFA performance report cutoff dates By review group and fiscal year received



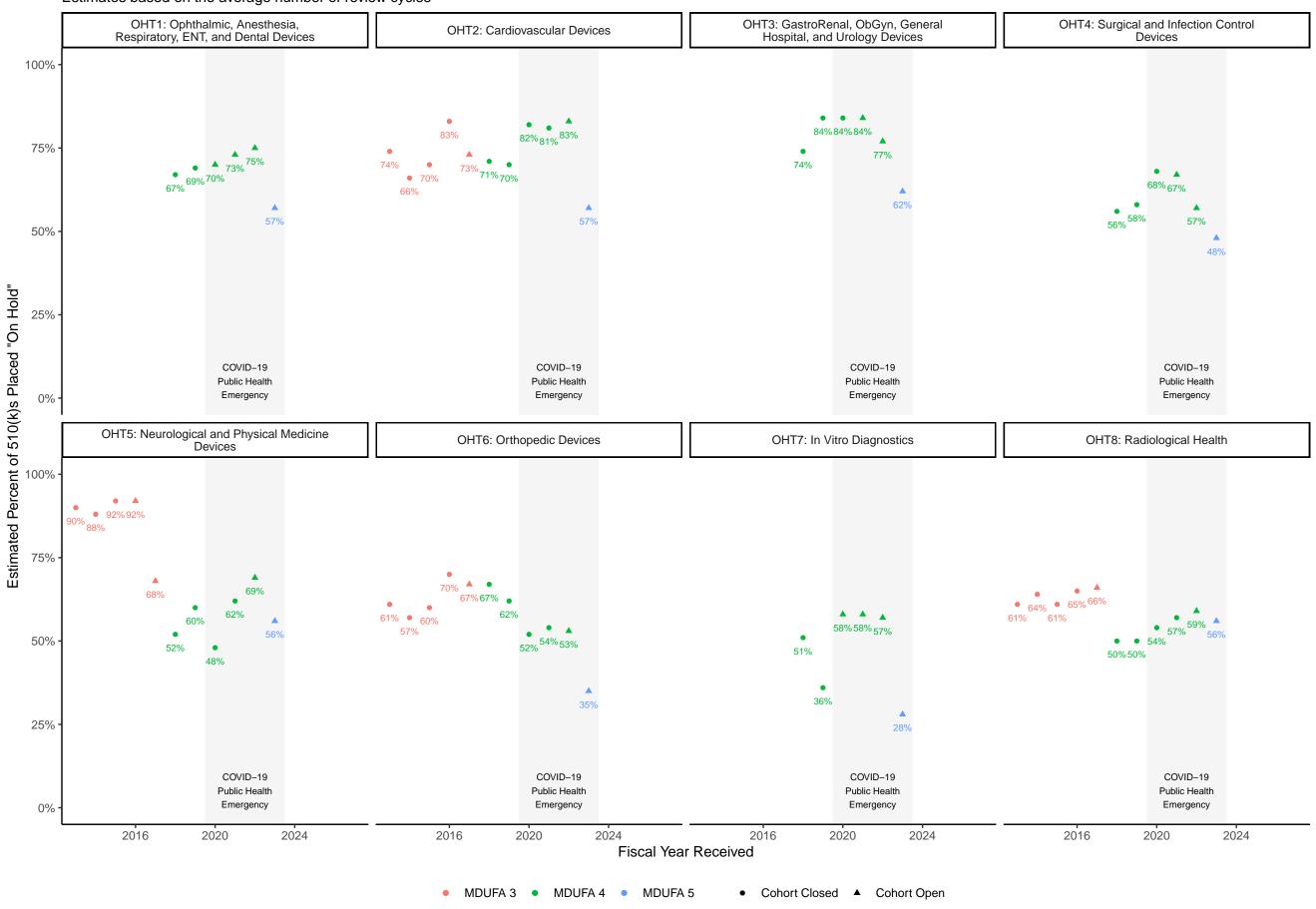
510(k) Total Days performance metrics as of MDUFA performance report cutoff dates

By review group and fiscal year received Values above 270 Total Days are not shown





By review group and fiscal year received Estimates based on the average number of review cycles



Rate at which 510(k)s are cleared for market as of MDUFA performance report cutoff dates By review group and fiscal year received OHT1: Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices OHT4: Surgical and Infection Control OHT3: GastroRenal, ObGyn, General OHT2: Cardiovascular Devices Hospital, and Urology Devices **Devices** COVID-19 COVID-19 COVID-19 COVID-19 Public Health Public Health Public Health Public Health Emergency Emergency Emergency Emergency 100% 75% 50% 25% Decision Rates (%) OHT5: Neurological and Physical Medicine OHT6: Orthopedic Devices OHT7: In Vitro Diagnostics OHT8: Radiological Health Devices COVID-19 COVID-19 COVID-19 COVID-19 Public Health Public Health Public Health Public Health Emergency Emergency Emergency Emergency 100% 75% 50% 25% 2015 2020 2025 2015 2020 2025 2015 2020 2025 2015 2020 2025 Fiscal Year Received Withdrawn or Deleted (Not Cleared) NSE (Not Cleared) SE (Cleared) Cohort Closed ▲ Cohort Open