MANDATORY	VOLUNTARY
Medical device **premarket notifications**: 510(k) and De Novo (unless exempted)	Medical device **premarket approval applications and supplement types**: Original PMAs, PMA Panel Track Supplements, PMA Real-Time Supplements, PMA 180 Day Supplements and 30-Day Notice/135-Day Supplements.
Dual 510(k)/CLIA Waiver IVD submissions to CDRH	**Q-Submissions** (Q-Sub), including Pre-Submissions, Submission Issue Requests, Informational Meetings, Study Risk Determinations, PMA Day 100 Meetings, and Accessory Classification Requests
	Investigational Device Exemptions (IDE)
	513(g) Requests for Information