

Requirement	Stage	Date	1976 Type	HLA for Trans.	Foren.	VHA / DoD	NY CLEP	Unmet Need	Curr. Mark.	Rare RBC Ant.	New LDT	Minor Mod. to Curr. Mark.	Signif. Mod. to Curr. Mark.	Minor Mod. to Other's 510(k)	Signif. Mod. to Other's 510(k)	Mod. Other's PMA
MDR, Correction, Removal (§ 803 and § 806)	1	5/6/25	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Complaint Files (§ 820.198)	1	5/6/25	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Registration (§ 807)	2	5/6/26	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Listing (§ 807)	2	5/6/26	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Labeling (§ 809.10)	2	5/6/26	No	No	No	No	Yes	Yes	Yes	No*	Yes	Yes	Yes	No**	Yes	Yes
Investig. Device (§ 812)	2	5/6/26	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Design Controls (§ 820.30)	3	5/6/27	No	No	No	No	Yes	No	No	No	Yes	No	Yes	Yes	Yes	Yes
Purchasing Controls (including supplier controls) (§ 820.50)	3	5/6/27	No	No	No	No	Yes	No	No	No	Yes	No	Yes	Yes	Yes	Yes
Acceptance Activities (receiving, in-process, and finished device acceptance) (§ 820.80 and § 820.86)	3	5/6/27	No	No	No	No	Yes	No	No	No	Yes	No	Yes	Yes	Yes	Yes
CAPA (§ 820.100)	3	5/6/27	No	No	No	No	Yes	No	No	No	Yes	No	Yes	Yes	Yes	Yes
Records (part 820, subpart M)	3	5/6/27	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Premarket Review (high risk); PMA	4	11/6/27	No	No	No	No	No	No	No	No	Yes	No	Yes	No	Yes	Yes
Premarket Review (moderate/low risk); 510(k) and de novo	5	5/6/28	No	No	No	No	No	No	No	No	Yes	No	Yes	No	Yes	N/A (PMA)

*FDA expects labs to maintain (but not submit) labeling. FDA Webinar, September 24, 2024. **Mod. scope limited to as described in the final rule preamble.



ant., antigen; CAPA, corrective and preventive action; curr., currently; DoD, Department of Defense; foren., forensic; HLA, human leukocyte antigen; investig., investigational; mark., marketed; MDR, medical device reporting; mod., modification; NY CLEP, New York Clinical Laboratory Evaluation Program; PMA, premarket approval; RBC, red blood cell; signif., significant; trans., transplant; VHA, Veterans Health Administration

Please send comments/edits to jonathan.genzen@aruplab.com. See final rule for exact requirements.