ARUP LABORATORIES

Updated June 5, 2024

# FDA LDT Matrix

| Requirement | Stage | Date | 1976-Type | HLA for Transplant | Forensic | VHA/DoD | NY CLEP | Unmet Need | Currently Marketed | Rare RBC Antigens | New LDT | Minor Mod. to Curr. Mark. | Signif. Mod. to Curr. Mark. | Mod. Other's 510(k) | Mod. Other's PMA |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **MDR, Correction, Removal** (§ 803 and § 806) | 1 | May 6, 2025 | No | No | No | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| **Complaint Files** (§ 820.198) | 1 | May 6, 2025 | No | No | No | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| **Registration** (§ 807) | 2 | May 6, 2026 | No | No | No | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| **Listing** (§ 807) | 2 | May 6, 2026 | No | No | No | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| **Labeling** (§ 809.10) | 2 | May 6, 2026 | No | No | No | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| **Investigational Device** (§ 812) | 2 | May 6, 2026 | No | No | No | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| **Design Controls** (§ 820.30) | 3 | May 6, 2027 | No | No | No | No | Yes | No | No | No | Yes | No* | Yes | Yes | Yes |
| **Purchasing Controls** (including supplier controls) (§ 820.50) | 3 | May 6, 2027 | No | No | No | No | Yes | No | No | No | Yes | No* | Yes | Yes | Yes |
| **Acceptance Activities** (receiving, in-process, and finished device acceptance) (§ 820.80 and § 820.86) | 3 | May 6, 2027 | No | No | No | No | Yes | No | No | No | Yes | No* | Yes | Yes | Yes |
| **CAPA** (§ 820.100) | 3 | May 6, 2027 | No | No | No | No | Yes | No | No | No | Yes | No* | Yes | Yes | Yes |
| **Records** (part 820, subpart M) | 3 | May 6, 2027 | No | No | No | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| **Premarket Review** (high risk); PMA | 4 | Nov 6, 2027 | No | No | No | No | No | No | No | No | Yes | No | Yes | No | Yes |
| **Premarket Review** (mod/low risk); 510k and De Novo | 5 | May 6, 2028 | No | No | No | No | No | No | No | No | Yes | No | Yes | No | N/A (PMA) |

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

*Pending clarification.