Last updated September 2023

Comparison of Diagnostic Reform Proposals

Issue	Current Version of VALID Act (March 2023)	FDA Proposed Rule (September 2023)
Description of "product" subject to regulation		
Name	*In vitro* clinical test (IVCT) [pg. 2]	Medical device [pg. 1]
Applies to LDTs?	Yes [pg. 2]	Yes [pg. 1]
New regulatory category?	Yes (though cross-reference to many requirements for medical devices) [pgs. 1-5]	No (considered a medical device) [pg. 1]
Grandfathering		
In general	**Grandfathered if first offered for clinical use *within 45 days of enactment*** Grandfathering extends to premarket review, labeling and QSR—but other requirements (*e.g.*, registration/listing) apply. Exceptions: • If modified in way that would require supplemental premarket submission if already approved • If insufficient evidence of analytical validity or clinical validity • If marketed with any false or misleading analytical or clinical claims • If probable that test will cause serious adverse health consequences).	**No grandfathering (in general)** The only tests that remain under enforcement discretion are pre-1976-Type LDTs, HLA tests performed in single laboratory, tests intended solely for forensic purposes and tests for public health surveillance (where results are not reported back to patients or providers). To the extent commenters request that FDA grandfather additional types of tests, FDA requests the following: • Explanation of "public health rationale" for grandfathering, including supporting data • Steps to help support a grandfathering approach, including ideas to help address FDA's concerns about LDT performance.

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	[pgs. 102–111]	FDA requests comments on whether it should continue enforcement discretion for tests offered at academic medical centers. [pgs. 55–57]
Timeline		
	In general, effective *October 1, 2028* Registration/listing and preemption may be implemented beginning on October 1, 2024, but not take effect until October 2028. "Transitional tests" (*i.e.*, tests first offered between the cutoff for grandfathering and October 1, 2028) may remain on the market after the effective date, provided the developer does one of the following: • Submits an application within 90 days of the effective date (for a "high-risk" test) • Lists the test within 10 days and submits an application for the test within one year of the effective date (for a "moderate-risk" test). **Transitional tests that have been approved by NYS may remain on the market without premarket review if they submit an application to FDA within:** • **Five years after the effective date (*October 1, 2033*) for genetic tests, microbiology**	**Phase-out of enforcement discretion to occur in stages over a *period of four years* "after FDA publishes a final phase-out policy"** • Phase 1 (effective one year post-finalization): end enforcement discretion with respect to medical device (adverse event) reporting, and correction/removal reporting requirements • Phase 2 (effective two years post-finalization): end enforcement discretion with respect to all other device requirements (*e.g.*, registration/listing, labeling, investigational use), except for quality systems and premarket review • Phase 3 (effective three years post-finalization): end enforcement discretion for QSR • **Phase 4 (effective three and a half years post-finalization, *but not before October 1, 2027*): end enforcement discretion for premarket review requirements for high-**

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	molecular tests, oncology molecular tests or other molecular tests • **Two years after the effective date (*October 1, 2030*) for all other tests.** [pgs. 220–230]	**risk tests (*i.e.*, tests subject to PMA requirement)** • Phase 5 (effective four years post-finalization, but not before April 1, 2028): end enforcement discretion for premarket review requirements for moderate- and low-risk tests (*i.e.*, tests subject to *de novo* or 510(k) requirement). Tests can remain on market while under FDA review (provided application submitted on time). FDA seeks comment on whether there is a public health rationale to support a longer phase-out period for labs with annual receipts below a certain threshold (*e.g.*, $150,000). [pgs. 56, 58–68]
Categorization		
Framework	Replaces device categorization with three-tiered, risk-based, diagnostic-specific framework (high, moderate and low risk) [pgs. 8, 12, 14]	Uses existing medical device classification structure (three classes, risk-based) [pgs. 27–29]
Recategorization	Yes (up- and down-classification) [pgs. 48–50, 95–100]	Yes (via *de novo* or 513(f)(3) process)
Premarket review requirements		

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General requirements	Must establish analytical and clinical validity (unless exempt); must also establish safety for individuals coming into contact with IVCT [pgs. 5–6, 15–17]	Depends on premarket review pathway for test: • PMA – "sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s)" • 510(k) – "demonstration of substantial equivalence to another legally U.S. marketed device" • *De novo* – "novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device."
High-risk tests	Submission req'd	Submission req'd—generally subject to PMA requirement
Moderate-risk tests	Submission req'd (via abbreviated review pathway) [pg. 27]	Submission req'd—generally subject to *de novo* or 510(k) requirement
Low-risk tests	No submission req'd, but subject to other requirements [pgs. 48–50]	In general, no submission req'd—but subject to other requirements
Allows for use of third-party reviewers	Yes [pgs. 147–163]	Yes (for certain types of devices) [pgs. 67–68]
Precertification pathway	Exempt from premarket review, but subject to other regulatory requirements	No (not available under current framework)

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	Clarifies that high-risk IVCTs are not eligible, as well as first-of-a-kind tests (unless moderate complexity, as determined by Secretary) [pgs. 66–91]	
Tests for emergency use	Submission req'd (via EUA pathway) [pgs. 234–237]	Submission req'd (via EUA pathway)
"Breakthrough" tests	Submission req'd, but expedited pathway to market (as part of broader "breakthrough" designation) [pgs. 114–119]	Leverages existing "breakthrough" device pathway
"Custom" tests	Exempt from premarket review, QSR and listing, but subject to other requirements [pgs. 53–55]	Only exempt from PMA requirements (not exempt from QSR, MDR, labeling, registration/listing)
Academic medical center laboratory exemption	No	No (but accepting comments on whether appropriate for grandfathering from premarket review and QSR) [pgs. 56–57]
Modifications		
Supplemental application	Required if change: • Constitutes a significant change to the indications for use (not counting changes to specimen type specified in guidance) • Causes the test to no longer comply with mitigating measures, significantly changes performance claims, or significantly and adversely changes performance, unless provided for in a change protocol	Required if change: • Affects safety or effectiveness of device (if PMA) • Represents a significant change or modification in design, components, method of manufacture, or intended use, where a significant change or modification is one that could significantly affect the safety or effectiveness of the device or is a major

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	• Adversely changes the safety of the IVCT for users • Means that test is likely to cause or contribute to serious adverse health consequences. [pgs. 55–60]	change or modification in the device's intended use (if 510(k)). [pg. 21]
Pre-approval of protocol allowing certain modifications without new premarket submission	Yes [pgs. 25, 59]	Yes
Quality systems		
In general	Generally mirror device QSR, but truncated list for laboratory offering high-complexity testing: • Design controls • Acceptance activities • Corrective and preventive action • Complaints and records. Clarifies that "lab operations" will remain under CLIA [pgs. 127–132]	Tests offered in single CLIA-certified laboratory subject to subset of usual "device" QSR. For tests where all manufacturing activities occur within a single CLIA-certified clinical laboratory and for which distribution does not occur outside that single laboratory, FDA expects compliance with some, but not all, QSR. Specifically, labs must comply with the following: • Design controls (21 CFR 820.30) • Purchasing controls (21 CFR 820.50) • Acceptance activities (21 CFR 820.80 and 820.86) • Corrective and preventive actions (820.100) • Records requirements (21 CFR 820, Subpart M).

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		For all other IVDs offered as LDTs, FDA proposes to end enforcement discretion for all QSR three years after finalization. [pgs. 62–64]
Clarifies that lab operations will remain under CLIA	Yes [pg. 130]	No
Postmarket controls		
Registration	Yes [pgs. 119–121]	Yes
Listing	Yes [pgs. 121–127]	Yes
Inspection	Yes [pgs. 121, 213–215]	Yes
Adverse event reporting	Yes [pgs. 138–140]	Yes
Postmarket surveillance	Yes (for subset) [pgs. 186–188]	Yes
Postmarket studies	Yes [pg. 257]	Yes
Recalls, corrections, removals and notification	Yes [pgs. 140–142]	Yes
Withdrawal or temporary suspension of approval	Yes	Yes

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	[pgs. 42–45]	
Investigational use		
In general	Yes [pgs. 164–177]	Yes
Preemption		
Relationship to state and local requirements	Preempts certain state and local requirements; states retain authority to license labs/personnel, and to authorize labs to develop and perform tests if law enacted by state before January 2022 and does not impose requirements that are "different from" federal requirements under VALID [pgs. 179–180]	No preemption
User fees		
In general	Yes (amount TBD – to be negotiated in manner generally consistent with other FDA user fee negotiation processes) [pgs. 243–271]	Yes (consistent with existing user fees for medical devices—*i.e.*, for FY 2024): • Establishment registration: $7,653 • 510(k): $21,760 • PMA: $483,560 • *De novo*: $145,068 (PMA, 510(k) and *de novo* fees subject to 75% reduction for FDA-certified "small business")
CLIA modernization		
In general		