

Proposed Timeline of Implementation

- | | |
|--|--|
| <u>October 1, 2014</u> | <ul style="list-style-type: none">• Publication of LDT draft guidance, and the opening of docket for public comments. |
| <u>Fall 2014</u> | <ul style="list-style-type: none">• Public stakeholder meeting. |
| <u>Final Guidance date (FG)</u> | <ul style="list-style-type: none">• Issuance of final guidance will trigger the new regulatory framework.• New highest risk LDTs must comply with premarket review requirements. Category includes tests with the same intended use as a cleared or approved companion diagnostic or an approved Class III medical device. |
| <u>FG + 6 months</u> | <ul style="list-style-type: none">• Deadline for all LDT laboratories to begin complying with either notification, or registration and listing requirements.• Deadline to begin complying with medical device reporting requirements. |
| <u>FG + 12 months</u> | <ul style="list-style-type: none">• FDA begins enforcing premarket review for highest risk LDTs that existed before the issuance of the final guidance. |
| <u>FG + 24 months</u> | <ul style="list-style-type: none">• Publication of a priority list for Class III high risk LDTs. |
| <u>FG + 36 months</u> | <ul style="list-style-type: none">• FDA begins enforcing premarket review for other Class III LDTs, beginning with higher risk LDTs, including LDTs that act like companion diagnostics, screening LDTs for asymptomatic patients without confirmatory diagnostic, and LDTs diagnosing certain infectious diseases and other high risk uses. |
| <u>FG + 4 years</u> | <ul style="list-style-type: none">• Publication of the prioritization of moderate risk (Class II) LDTs. |
| <u>FG + 5 years</u> | <ul style="list-style-type: none">• FDA completes the phase in of premarket review enforcement for Class III LDTs, and proceeds to enforcement of premarket review requirements for Class II LDTs. |
| <u>FG + 9 years</u> | <ul style="list-style-type: none">• FDA completes the phase in of premarket review enforcement for Class II LDTs. |