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Faster Review • Faster Clearance • Faster Product Launch

Food and Drug Administration (FDA) 510(k) review is required for a medical device to be marketed in the United States. Third Party Review is an alternative that can be faster than a traditional FDA 510(k) review. COLA's team of scientific experts, regulatory leaders and workflow professionals provide thorough and accelerated review of 510(k) applications. Companies that use Third Party Review are exempt from paying the FDA's Medical Device User Fee Amendments (MDUFA) user fee and instead pay a fee to COLA for the review.

First Name*

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How COLA helps your device get to the market faster.

