PMA Request Review Process

PMA Application Submitted

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Acceptance Review

The FDA ensures applications contain all necessary elements.

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Filling Review

The FDA makes a threshold determination that a PMA is complete and ready for an in-depth review.

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Substantive Review

The FDA looks for application deficiencies, and applications are placed on hold if deficiencies exist.

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NOTE:
Review process may change if the FDA conducts a Panel Meeting or Pre-Approval Inspection

Interactive Review

Companies maintain communication with the FDA by responding to minor application deficiencies and negotiating product labeling.

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PMA Decision

Approval Order	Approval Letter	Letter for Not Approval	Order Denying Approval
The product is approved by the FDA, but companies must submit a printed copy of their product's final labeling before entering the market.	If companies submit additional information or agree to a specific list of conditions, the FDA can approve device applications.	The FDA is unable to approve an application at this time due to a need for additional information to determine safety and effectiveness.	Applications are disapproved because companies failed to address PMA requirements.