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.

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