# **MARKET ACCESS TO US (510K)**



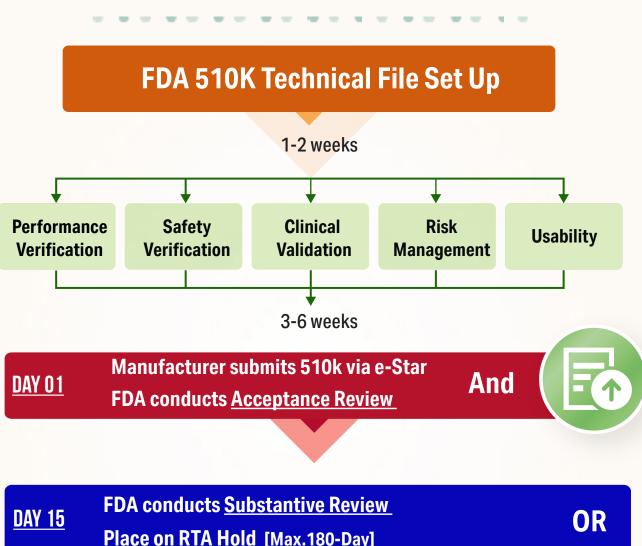




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## 510K Notification PROCESS



Place on RTA Hold [Max.180-Day]

FDA proceeds with **Interactive Review** Place On hold **DAY 60** for Additional Information [Max.180-day]

OR

**DAY 90** 

510k Approval



# **MARKET ACCESS TO US (510K)**



# **DOCUMENTS REQUIRED**

<b>✓</b>	Medical Device User Fee Cover Sheet (Form FDA 3601)
<b>/</b>	CDRH Premarket Review Submission Cover Sheet
<b>/</b>	510(k) Cover Letter
<b>/</b>	Indications for Use Statement
<b>✓</b>	510(k) Summary or 510(k) Statement
<b>✓</b>	Truthful and Accuracy Statement
<b>✓</b>	DOC and Summary Reports
<b>✓</b>	Executive Summary
<b>✓</b>	Device Description
<b>✓</b>	Substantial Equivalence Discussion
<b>✓</b>	Proposed Labeling
<b>✓</b>	Risk Management
<b>✓</b>	Sterilization and Shelf Life
<b>✓</b>	Biocompatibility
<b>✓</b>	Software and Cybersecurity
<b>V</b>	EMC and Electrical Safety
<b>V</b>	Performance Testing - Bench
<b>/</b>	Performance Testing - Animal
<b>V</b>	Performance Testing - Clinical

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