Association for the Advancement of Blood & Biotherapies

AABB is an FDA-Accredited 510(k) Third-Party Reviewer

AABB Can Help Speed Clearance for Eligible Lower-Risk FDA 510(k) Devices

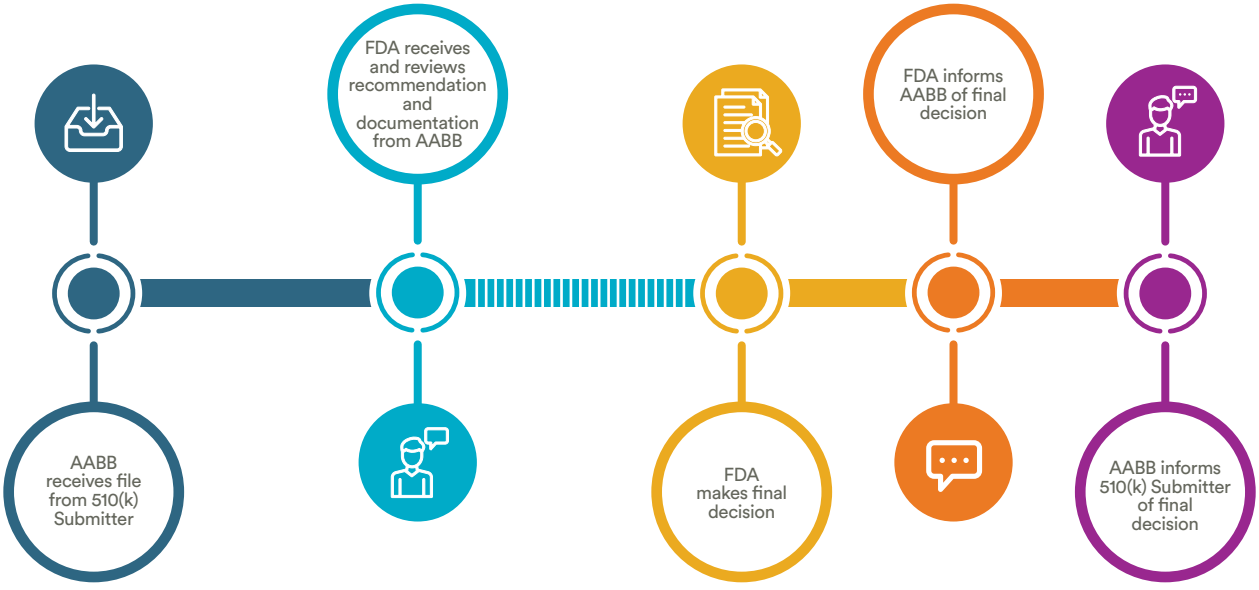
AABB can help companies with 510(k) clearance for a number of eligible laboratory and general medical devices. The Association is approved by the FDA as a third-party reviewer to help expedite the device clearance process. The FDA's **510(k) Third Party Review Program** offers a voluntary alternative review process, in which accredited third party review organizations – such as AABB – are permitted to review certain low-to-moderate risk pre-market medical device submissions.

Helping FDA Meet Demand for Lower-Risk Device Clearances

The FDA initiated this program to provide more rapid 510(k) decisions for lower-risk devices and to allow the Agency to focus its resources on higher-risk devices. As a third-party reviewer, AABB has been invited to work directly with companies, facilitating FDA review and clearance.

How It Works

The process allows manufacturers to submit 510(k) lower-risk device premarket applications directly to AABB. The Association's experts then review each submission and makes recommendations to the FDA. The Agency maintains oversight of the review process and grants the final approval. AABB then shares the decision with the applicant. All fees for the submission are paid to AABB.



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Devices That AABB Can Help Expedite

AABB is accredited to review the premarket submissions for eligible device types regulated as hematology, pathology, microbiology, general hospital and clinical chemistry devices, including:

CLINICAL CHEMISTRY

- Blood specimen collection devices
- General purpose laboratory equipment labeled or promoted for a specific medical use

HEMATOLOGY

- Multipurpose system for in vitro coagulation studies
- Automated platelet aggregation system
- Fetal hemoglobin assay
- Whole blood hemoglobin assays
- Heparin assay
- Prothrombin time test
- Sickle cell test

MICROBIOLOGY

- Antimicrobial susceptibility test disc
- Culture medium for antimicrobial susceptibility tests
- Microbial growth monitor

GENERAL HOSPITAL

- Sterilization process indicator
- Clinical electronic thermometer
- Intravascular administration set
- Hypodermic single lumen needle
- Non-powdered patient examination glove.

The full list of eligible device types that AABB is eligible to review is available on the **FDA website**.

Let AABB Help You Through the Clearance Process

For more information on how AABB can help you get devices through the clearance process more quickly, **contact AABB** to find out the steps and requirements of the 510(k) review process.

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