



## FDA - Accreditation Scheme for Conformity Assessment (ASCA) For Premarket Submission of Medical Devices

### ***ITL - FDA ASCA Accredited Laboratory = Faster FDA Premarket Submission***

The voluntary ASCA Program is intended to enhance product reviewers' and device manufacturers' confidence in medical device testing, which should **decrease the need for the FDA to request additional information regarding testing methodologies when a premarket submission includes declarations of conformity to an FDA-recognized consensus standard eligible for inclusion in the ASCA Program.** Ultimately, the ASCA Program is intended to help the FDA ensure patients have timely and continued access to safe, effective, and high-quality medical devices.

FDA grants *ASCA Recognition* to qualified testing laboratories to perform premarket testing for medical device companies. Relying upon international conformity assessment standards and a set of FDA-identified ASCA program specifications, the ASCA program is intended to increase consistency and predictability in the FDA's approach to assessing conformance with FDA-recognized consensus standards and test methods eligible for inclusion in the ASCA for medical device premarket reviews.

The device manufacturer includes the ASCA summary test report with its own declaration of conformity in a premarket submission to the FDA.

## **Why the FDA Is Launching the ASCA Program**

The ASCA Program supports the FDA's public health mission by providing increased confidence in testing results from ASCA-accredited testing laboratories. The ASCA Program:

- Potentially decreases the burden of individual premarket submissions when manufacturers rely on testing completed by ASCA-accredited testing laboratories
- Incorporates existing international conformity assessment standards and practices where practical

### Benefits:

Potentially decreases the burden of individual premarket submissions when manufacturers rely on testing completed by ASCA-accredited testing laboratories

ASCA Program: Key Facts

**Basic Safety and Essential Performance standards-specific guidance:** *Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program.*

## **How the ASCA Program Works**

A device manufacturer may choose to use an ASCA-accredited testing laboratory to conduct testing for premarket submissions to the FDA.

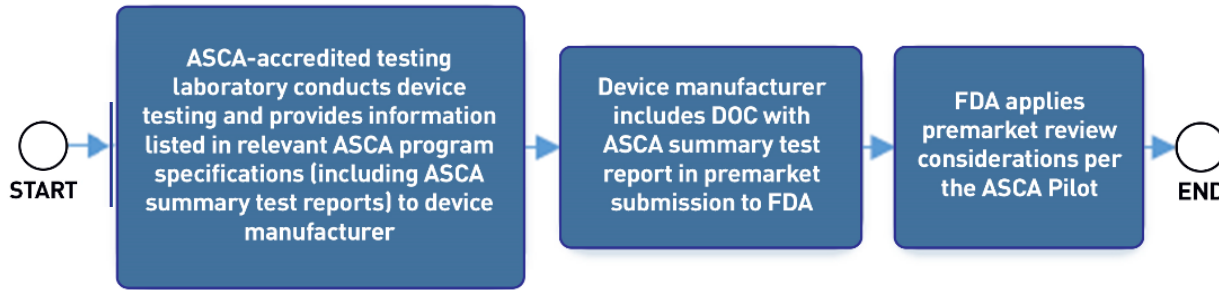


Figure: Process flow for the ASCA

## Basic safety and essential performance standards included in the ASCA Program

Standard	Standard Title
ANSI/AAMI 60601-1	<i>Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (along with the FDA-recognized collateral and particular standards in the IEC/ISO 60601/80601 family)</i>
IEC 61010-1	<i>Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements (along with the FDA-recognized particular standards in the IEC 61010 family)</i>

Manufacturers should continue to rely on other FDA-recognized standards and provide declarations of conformity in premarket submissions (see [Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#))

## Manufacturer Participation

Device manufacturers may voluntarily use an ASCA-accredited testing laboratory to conduct testing to be included in premarket submissions to the FDA. A device manufacturer using an ASCA-accredited testing laboratory to perform testing under the ASCA Program includes a declaration of conformity with any necessary supplemental documentation (for example, an ASCA summary test report) as part of a premarket submission.

The ASCA Program does not alter the device manufacturer's responsibility to address relevant information in a premarket submission. This includes documenting how testing supports marketing authorization, even when the testing is performed by an ASCA-accredited testing laboratory.

**No Requirement to Apply:** There is no application process for manufacturers to participate in the ASCA Program but only to submit testing accompanied by a declaration of conformity as well as appropriate supplemental documentation (e.g., an ASCA summary test report)



**Eligible Devices and Submissions:** Testing performed by an ASCA-accredited testing laboratory can be used to support a premarket submission for any device, including device submissions for combination products.

**FDA's Review of ASCA-Accredited Testing:** ASCA-accredited testing laboratories agree to use methodologies consistent with the FDA-recognized consensus standards and test methods in their scope of *ASCA Accreditation* and the relevant ASCA program specifications. The FDA generally intends to rely on the results from ASCA-accredited testing laboratories for the purpose of premarket review without the need for additional information related to conformance with a standard when:

- The testing is accompanied by a declaration of conformity as well as appropriate supplemental documentation (e.g., an ASCA summary test report) and
- The standard and test methods are within the testing laboratory's scope of *ASCA Accreditation* at the time of testing

In addition, the FDA does not intend to question the validity of test methods within a testing laboratory's scope of *ASCA Accreditation* except in the circumstances outlined in the ASCA program guidance.

**Manufacturer's Responsibilities for Premarket Submissions:** The device manufacturer is responsible for providing all relevant information in a premarket submission. This includes documenting how testing supports marketing authorization, even when the testing is performed by an ASCA-accredited testing laboratory.

Note that the ASCA-accredited testing laboratory provides to the device manufacturer all information listed in the relevant ASCA program specifications (including the ASCA summary test report). The device manufacturer then includes the appropriate supplemental documentation (for example, the ASCA summary test report) with its own declaration of conformity in a premarket submission to the FDA.