

UL's participation in the FDA ASCA Pilot program



UL can help you meet compliance requirements with premarket testing for medical devices with our FDA-recognized ASCA testing laboratories worldwide.

Summary

The U.S. Food and Drug Administration (FDA)'s voluntary ASCA Pilot program works to improve the efficiency of a premarket review and enhance FDA product reviewers' and device manufacturers' confidence in medical device testing when performed by an ASCA-accredited laboratory. Utilizing FDA-recognized consensus standard(s) eligible for inclusion in the ASCA Pilot program helps minimize requests for additional information during premarket submissions. As the global safety science leader and with ASCA-accredited laboratories all over the world, UL can provide stringent, reliable product testing to help you meet the FDA's regulatory requirements.

According to the FDA, "Testing performed by an ASCA-accredited testing laboratory can be used to support a premarket submission for any device if the testing was conducted using an FDA-recognized consensus standard and test method eligible for inclusion in the ASCA Pilot and in accordance with the ASCA program specifications for that standard." It is important to note that not all FDA-recognized consensus standards will be included in the ASCA Pilot. UL's FDA ASCA scope of accreditation covers the majority of standards included within the program.

We offer ASCA-accredited laboratory testing of medical devices at nine locations globally, including five labs in North America, two in Asia and two in Europe.

Benefits and goals

- Helps lessen the chances of repeat or revised testing and reduces requests for more information by FDA reviewers
- May save time and money spent with limited documentation requirements
- Helps build confidence in medical device testing performed at the accredited laboratory
- Provides flexibility and consistency in the premarket review process, ranging from a single test to certifications, depending on the manufacturer's needs
- Assists medical device manufacturers in meeting the FDA's regulatory requirements



Process

Below is the high-level process the FDA provides:

-  Device manufacturers select an ASCA-accredited testing laboratory for device testing.
-  The laboratory conducts device testing and provides information listed in relevant ASCA program specification (including summary test reports) to the device manufacturer.
-  The device manufacturer includes DOC with ASCA summary test report in the premarket submission to the FDA.
-  The FDA applies premarket review consideration per the ASCA Pilot.

Our FDA ASCA laboratory offerings

Region	Americas	Europe	Asia
Locations	<ul style="list-style-type: none">Brea, CaliforniaFremont, CaliforniaMounds View, MinnesotaNorthbrook, IllinoisMelville, New YorkResearch Triangle Park, North Carolina	<ul style="list-style-type: none">Neu Isenburg, GermanyWarsaw, PolandMilan, Italy	<ul style="list-style-type: none">Ise-Shi Mie-Ken, JapanGuangzhou, ChinaSuzhou, ChinaTaipei, Taiwan
Specialties	<ul style="list-style-type: none">Patient monitoringImagingApplied energy	<ul style="list-style-type: none">Patient monitoringImaging	<ul style="list-style-type: none">Patient monitoringImagingApplied energy
Collaterals	<ul style="list-style-type: none">X-rayAlarmsHome useEmergency medical	<ul style="list-style-type: none">X-rayAlarmsHome useEmergency medical	<ul style="list-style-type: none">X-rayAlarmsHome use
EMC	<ul style="list-style-type: none">Fremont, CaliforniaNorthbrook, IllinoisResearch Triangle Park, North Carolina	<ul style="list-style-type: none">Milan, Italy	<ul style="list-style-type: none">Guangzhou, ChinaTaipei, Taiwan

How UL can help

UL's experts have a deep understanding of and long history of working with the evolving standards landscape for healthcare applications worldwide. We offer global, comprehensive testing and certification services through ASCA-accredited laboratories throughout the entire product life cycle.

To learn more about ASCA, visit [UL.com/services/fda-asca-pilot-program](https://www.ul.com/services/fda-asca-pilot-program) or contact your local sales representative.



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