Understanding the FDA ASCA Pilot Program

BRINGING YOUR MEDICAL DEVICE TO MARKET FASTER

WHAT IS THE ASCA PILOT PROGRAM?

The FDA developed the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program to make premarket testing of in vitro diagnostic (IVD) products and medical devices more consistent and efficient.

It reduces the regulatory burden for medical device manufacturers by relying on the product review and testing process carried out by the ASCA-accredited laboratory. The premarket submission to the FDA is more agile and convenient.

FDA ASCA Pilot Program Flowchart

Application

Accreditation bodies apply to FDA for ASCA Recognition.

ASCA Recognition

FDA grants ASCA Recognition to qualified accreditation bodies, including **TÜV SÜD.**

ASCA-Recognized Accreditation Bodies

Testing laboratories receive accreditation from ASCA-recognized accreditation bodies.

Laboratories' Application

Testing laboratories apply to FDA for ASCA Accreditation.

ASCA Accreditation

FDA grants ASCA Accreditation to qualified testing laboratories.

TÜV SÜD Receives ASCA Accreditation

FDA grants ASCA Accreditation to the medical device testing laboratories in the US and Canada.

California | **Massachusetts** | **Florida** | **Minnesota** | **Canada**

Manufacturers Select TÜV SÜD

Partnering with **TÜV SÜD** as the FDA ASCA-accredited laboratory for basic safety and performance testing of medical devices will allow manufacturers to access the most recognized experts in the field of medical testing to ensure a faster and more efficient FDA review process.

Planning and Timeline

Manufacturers and **TÜV SÜD** experts partner to review and submit documentation. Our experts will propose a plan and schedule.

Document Submission

Device manufacturer includes DOC with ASCA summary test report in premarket submission to FDA.

FDA Review

FDA applies premarket review considerations per the ASCA pilot.

We Are the Global Leader in Medical Device Testing and Certification

For over 30 years, TÜV SÜD has provided certification and testing services for manufacturers and suppliers of medical devices and in-vitro diagnostics. We have in-depth knowledge of the medical devices and IVD market, and our global team of experts provides assessments covering your product's entire life cycle.

TÜV SÜD America

www.tuvsud.com/en-us/ASCA

Source: FDA