PARTNERING WITH INTERTEK FOR THE



FDA ASCA PROGRAM



START

Accreditation Bodies apply to FDA for ASCA Recognition and FDA grants approval to qualified accreditation bodies



1

Intertek obtained ASCA Accreditation from the FDA in 2 Steps. **Step One:** Intertek was assessed by and received accreditation from an ASCA Recognized accreditation body to ISO / IEC 17025 and the ASCA Program specifications. **Step Two:** After gaining ASCA accreditation by the ASCA Recognized accreditation body, Intertek submitted its application to the FDA for final ASCA Accreditation.

Intertek Subject Matter Experts to

(related to test plan decisions and

essential performance), and any Test

Plan information, identify applicable

standards and provide proposal for

Information, IFU, Risk Management Files

review Medical RFQ, Product

testing and evaluation



2

Device Manufacturers select one of Intertek's 16 ASCA Accredited Testing Laboratories for Product Review, Evaluation and Testing.



2

6

5



Device Manufacturer to complete the Medical RFQ Form and select "FDA ASCA Program" to indicate interest in partnering with Intertek Intertek Medical Team to provide customized ASCA Test Plan (TP) Document for customer completion and review along with Medical Request for Quote (RFQ)



7

As an ASCA Accredited Testing Laboratory, Intertek, conducts device testing and provides information listed in relevant ASCA Program specifications (including ASCA Summary Test Reports) to Device Manufacturer along with any additional requested reports for ETL Classification (NRTL), CB Scheme, Informative IEC Test Reports, etc.



8

Device Manufacturer includes
Declaration of Conformity (DOC)
with ASCA Summary Test Report
in Pre-Market Submission to FDA



FINISH

FDA applies Pre-Market Review considerations per the ASCA Program

collaboration regarding Test Plan and finalize testing and evaluation approach - any changes to scope of testing or timeline to be identified

Intertek and Device Manufacturer

to continue partnership and