

# The ASCA Pilot: Streamlining Conformity Assessment in Device Submissions

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# ASCA Goal:

*Enhance the use of  
conformity  
assessment in  
premarket review*



# Learning Objectives

- Describe the Accreditation Scheme for Conformity Assessment (ASCA) Pilot and its benefits
- Describe premarket submission preparation with testing from ASCA-accredited test lab
- Discuss *Helpful Tips* for participating in the ASCA Pilot

# Introduction to ASCA Pilot

# What is the ASCA Pilot?

- Voluntary program
- Leverages a well-established international conformity assessment infrastructure
- Capitalizes on voluntary consensus standards in device development and review
- Puts “standards to work” on both individual and international levels

# Why ASCA?

- Enhances FDA's confidence in test methods and results
- Decreases need for additional information related to conformance with a standard
- Promotes consistency, predictability, and efficiency in medical device review
- Least burdensome approach to conformity assessment
- Patients have access to safe, effective, and high-quality medical devices

# Terminology

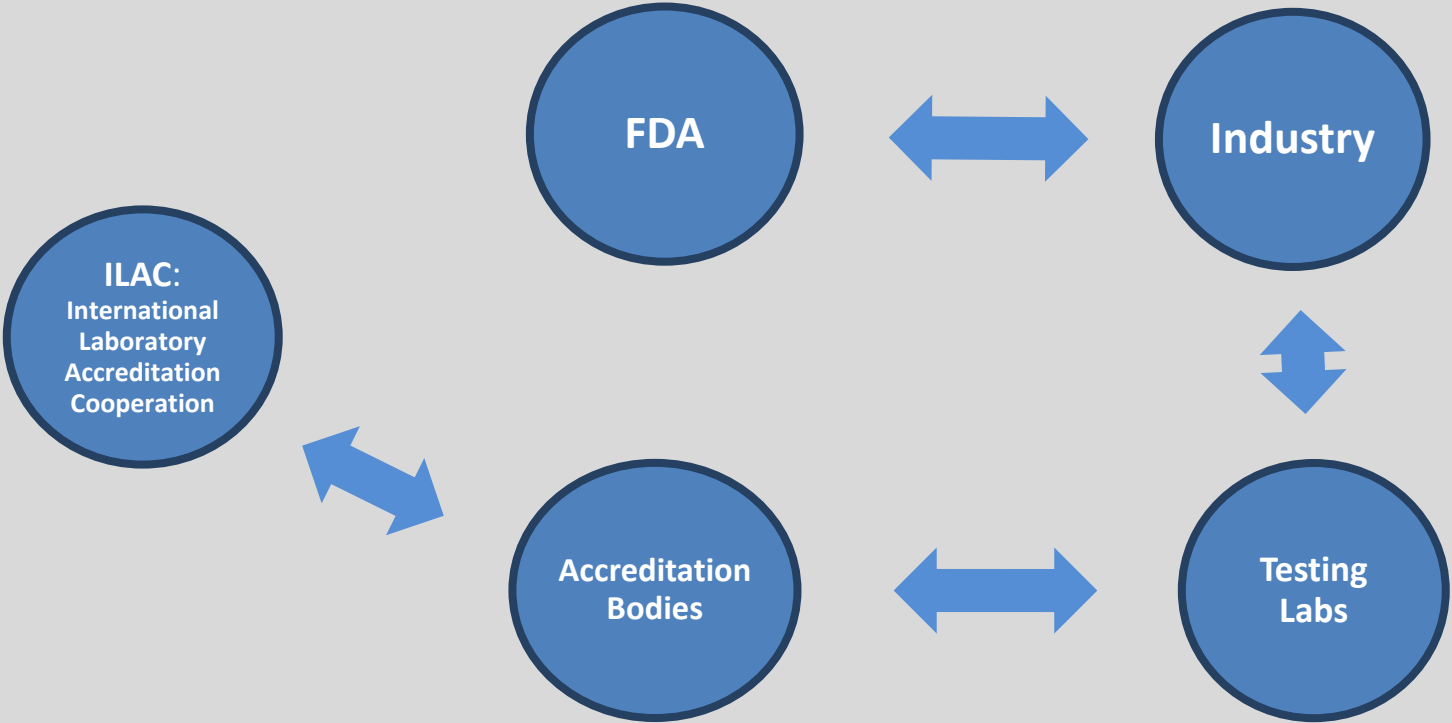
- **ASCA Recognition**

- Status granted by FDA to accreditation bodies
- Demonstrate competence in accreditation activities

- **ASCA Accreditation**

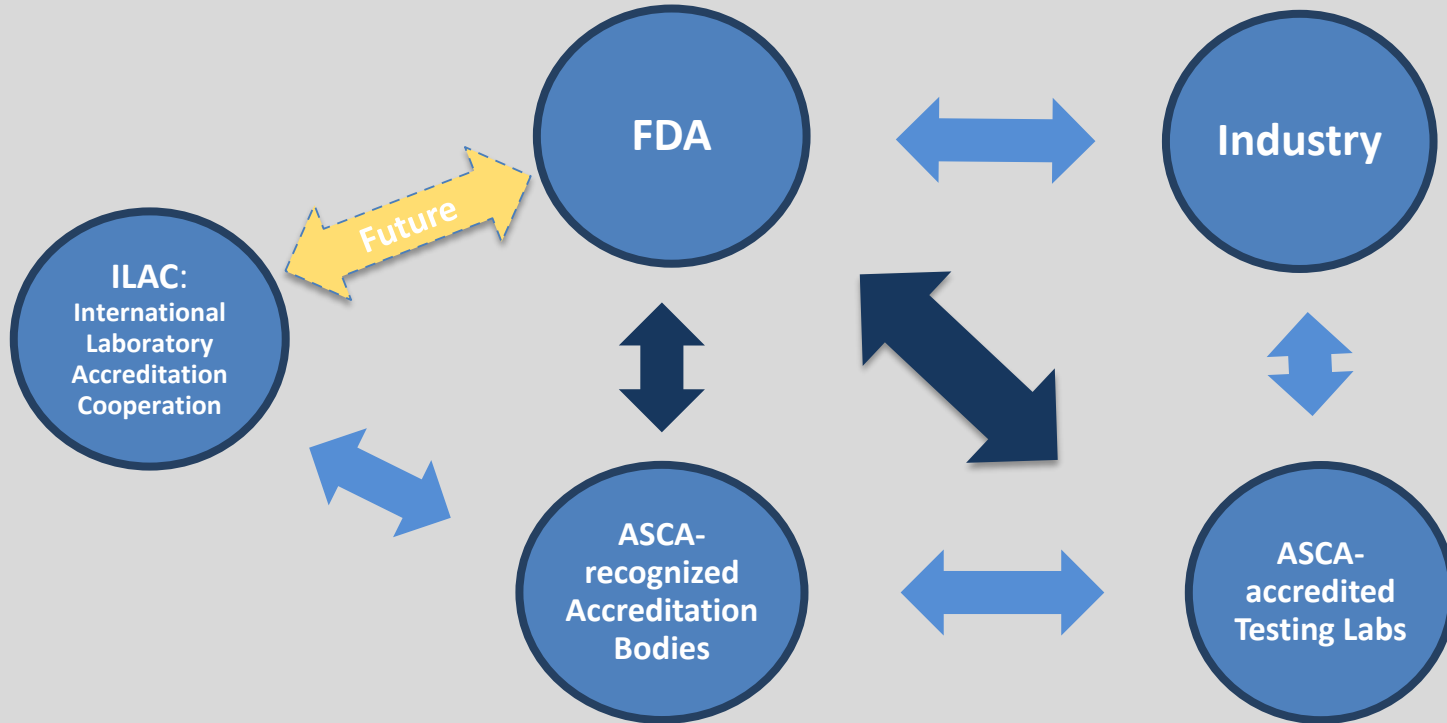
- Status granted by FDA to testing laboratories
- Demonstrate competence in testing through application process
- Described in ASCA Pilot program guidance

# Pre-ASCA Pilot Stakeholders

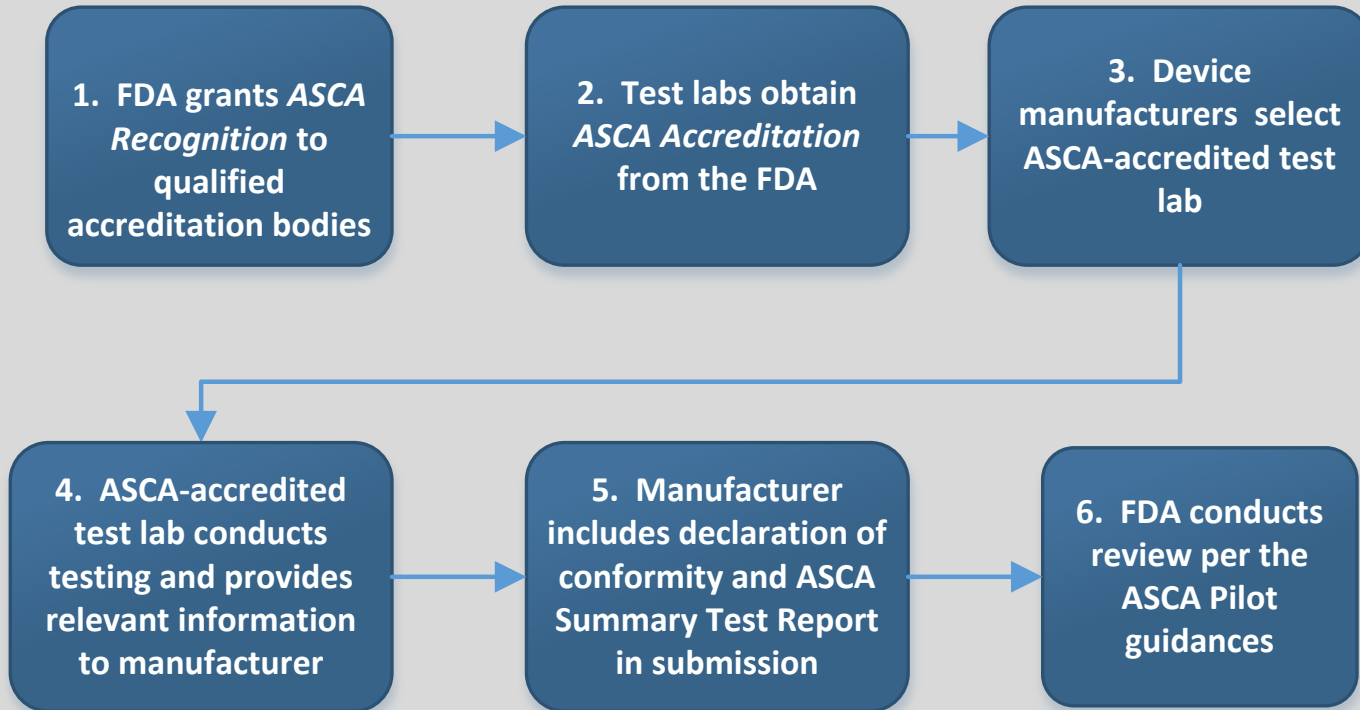




# ASCA Pilot Stakeholders



# How ASCA Works



# ASCA Pilot Guidances

- **Program**
  - Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program
  
- **Standards-Specific**
  - Biocompatibility Testing of Medical Devices
  - Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment

# ASCA Pilot Standards: Biocompatibility

FDA Recognized Consensus Standard	Test Method(s)
ISO 10993-4	Complement Activation using a U.S. marketed ELISA kit
ISO 10993-4 and ASTM F756	Direct and Indirect Hemolysis
ISO 10993-5	MEM Elution Cytotoxicity
ISO 10993-10	Dermal Irritation, Intracutaneous Reactivity Irritation, and Closed Patch Sensitization
ISO 10993-10 and ASTM F720	Guinea Pig Maximization Sensitization
ISO 10993-11	Acute Systemic Toxicity
ISO 10993-11 and USP 151	Material-Mediated Pyrogenicity
ISO 10993-12	Sample preparation for all test types

**\*\*\* Please see the Biocompatibility standards-specific guidance for a full listing of standards and test methods and visit the Recognized Consensus Standards database for more information \*\*\***

# ASCA Pilot Standards: Basic Safety and Essential Performance

Standard	Standard Title
ANSI/AAMI 60601-1	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)
IEC 61010-1	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)

**\*\*\* Please see the Basic Safety and Essential Performance standards-specific guidance for a full listing of standards and test methods and visit the Recognized Consensus Standards database for more information \*\*\***

# **Preparing Premarket Submissions with Testing from ASCA-accredited Testing Laboratories**

# Steps

- 1 Identify ASCA Pilot standards to be cited
- 2 Develop and agree on test plan with an ASCA-accredited test lab
- 3 Plan submission elements
- 4 Obtain results and Summary Test Report(s) from test lab
- 5 Prepare FDA submission

## Identify ASCA Pilot Standards to be Cited

- Check ASCA Pilot web page for ASCA standards
- Consult Recognized Consensus Standards database
  - Supplementary Information Sheet (SIS)
  - Standard's extent of recognition and edition

**\*\*\* Manufacturers are responsible for selecting and using FDA-recognized consensus standards and test methods appropriately \*\*\***



## Develop and Agree on Test Plan with ASCA-accredited Test Lab

- Select an ASCA-accredited testing laboratory
- Develop and agree on test plan
  - Note: Manufacturer is responsible for test plan(s)
  - Considerations:
    - Relevant FDA guidance documents
    - FDA-recognized consensus standards
    - Testing outside a testing laboratory's scope of *ASCA Accreditation*

## Plan Submission Elements

- Submission elements
  - Cover letter with ASCA-specific information
  - Declaration of Conformity (DOC)
  - Summary Test Report(s)
- Standards-specific guidances provide examples of DOCs and Summary Test Reports

**\*\* Complete test reports are generally not needed for ASCA Pilot standards \*\***

## Obtain Results and Summary Test Report(s) from Test Lab

- Testing laboratory
  - Conducts testing
  - Sends complete test reports and ASCA Summary Test Report(s) to manufacturer

## Prepare FDA Submission

- Cover letter with ASCA-specific information
- Declaration of conformity
- Summary Test Report(s)
  - Generally don't need complete test reports
  - Manufacturer should not modify Summary Test Reports from testing laboratories
- All other submission requirements

# ASCA Pilot

## Premarket Submission Elements

### Cover Letter

- States that submission is for ASCA Pilot
- Name, location and IDs of test lab(s)
- FDA-recognized consensus standard(s) and test methods used

### Declaration of Conformity (DOC)

- Manufacturer's responsibility
- *ASCA Accreditation* status for the test lab
- See suggested content in guidance

### ASCA Summary Test Report

- See standards-specific ASCA Pilot guidance documents for examples

**\*\* Device manufacturers are responsible for documenting how testing supports premarket authorization, even for ASCA Pilot submissions \*\***

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# Examples of ASCA DOCs

## **Appendix A: Example ASCA Declaration of Conformity (DOC) for Biological Evaluation of Medical Devices Standards in the ASCA Pilot**

*Note: This example is intended to illustrate elements of the Declaration of Conformity per FDA's guidance [Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#) that the device manufacturer may submit as part of its premarket submission.*

## **Appendix A: Example ASCA Declaration of Conformity (DOC) for Basic Safety and Essential Performance Standards in the ASCA Pilot**

*Note: This example is intended to illustrate elements of the Declaration of Conformity per FDA's guidance [Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#) that the device manufacturer submits as part of their premarket submission.*

# Summary Test Report, page 1

## Appendix B: Example ASCA Summary Test Report for Basic Safety and Essential Performance Standards in the ASCA Pilot

*Note: This example is intended to illustrate the supplemental documentation that should accompany the Declaration of Conformity per FDA's guidance [Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#). The ASCA summary test report is provided by the testing laboratory to the device manufacturer.*

### Administrative Information

1. Testing Laboratory Name:
2. ASCA Testing Laboratory Identification Number:
3. Testing Location(s):
4. Testing Date(s):
5. ASCA Accreditation Status on the Date(s) of Testing:
  - Standard was \*NOT\* in testing laboratory's scope of ASCA Accreditation
  - Standard was in testing laboratory's scope of ASCA Accreditation
    - ASCA Accreditation was not suspended
    - ASCA Accreditation was suspended

*Description of reasons for suspension and their impact on testing results.*


### Device Essential Performance Characteristics

*Description of the device essential performance characteristics supplied by the device manufacturer to the testing laboratory (including reference to any relevant particular standards with essential performance specified) and which were included in the testing. List any differences (if any identified) between the essential performance identified by the standard and the essential performance considered during the test. For multiple standards and/or multiple tests, include the essential performance characteristics used for each.*

### Use Environment

- Home Healthcare Environment [IEC 60601-1-11]
- Professional Healthcare Facility Environment
- Magnetic Resonance (MR) Environment
- Aircraft Environment
- Emergency Medical Services Environment [IEC 60601-1-12]
- Special / Other Environment

*Include any relevant details regarding the specified use environment here.*

**Clauses Tested**

1. Clauses Deemed Applicable
  - All clauses were deemed applicable.
  - The following clauses were deemed not applicable.

*List of and rationale for any clauses identified as not applicable*

2. Clauses Tested
  - All clauses were tested
  - The following clauses were not tested

*List of any clauses not tested.*

3. Clauses with Failing Results
  - No clauses had failing results
  - The following clauses had failing results

*List of any clauses with failing results. Descriptions of any failures.*

**Modification(s) to Test Methods and/or Acceptance Criteria**


- No test methods specified in the standard were modified
- No acceptance criteria specified in the standard were modified
- One or more test methods or acceptance criteria were modified

*List of test methods and/or acceptance criteria that were modified. Appropriate supporting documents should be attached to this ASCA summary test report including the test plan and procedure, acceptance criteria that were applied, and the test results.*

**Additional Testing Performed to Demonstrate Conformity with the Standard**

- No additional testing was performed other than that specified in the standard
- Additional testing was performed as specified by the manufacturer to address a hazardous situation not specifically addressed by the standard

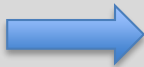
*Description of additional testing performed to address a hazardous situation not specifically addressed by the standard. Appropriate supporting documents are attached to this ASCA summary test report including the test plan and procedure, acceptance criteria that were applied, and the test results.*

**Device Configuration(s) and Mode(s) of Operation**

*Description of how device was configured including modes of operation used during testing.*

# Summary Test Report, page 2

# Summary Test Report, page 3



### Observations and Degradations During Testing

- Observations and degradations were NOT found during testing
- Observations and degradations were found, but deemed acceptable based on the pass/fail criteria identified by the device manufacturer

*Description of observations and degradations of concern to the testing laboratory but deemed acceptable. Example include:*

- *Instances of device showing unexpected behaviors (e.g., display of incorrect values, display of error messages, device or components need to be restarted, if the device or components restart unexpectedly).*
- *Instances of device or components being unexpectedly damaged and need replacement or other intervention to return to normal operation.*

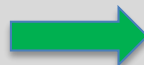
*This list should capture unexpected events. As an example, an error message would be unexpected (and therefore would be listed) during EMC testing when a valid input is present; conversely, the same error message would be expected (and therefore would not be listed) during a test that feeds an out-of-range input to verify the function of input errors. Any unexpected behavior is reported even if acceptable per the pass/fail criteria. If the unexpected behavior is listed as possible in the labeling (e.g., "the device may restart unexpectedly"), it would still be reported here.*



### Modifications to Test Article(s) During Testing

- No modifications were made to the test articles during testing
- Modifications were made to the test articles during testing. Description of modification including their impact on prior test outcome(s) are provided below.

*Description of modifications made to test articles during testing. Description of prior tests that were repeated based on modifications made or justification for not repeating prior tests.*



### Concerns Identified

- No concerns were identified.
- Concerns were communicated to the device manufacturer; see list below.

*List and description of concerns communicated to the device manufacturer.*



I confirm that:

- The above summary information includes all original and any retest data
- The above summary information is an accurate representation of the testing conducted

Name: [TYPED NAME POSITION]

Date

# Helpful Tips



# Helpful Tips

1. Include appropriate references to ASCA in cover letter
  - Test lab information
  - ASCA standards and/or test methods
2. Submit complete DOCs
  - for all cited FDA-recognized standards
3. Include ASCA Summary Test Report(s)
  - as supplied by the testing laboratory
4. Ask questions in advance
  - We're here to help!

# Summary

## The ASCA Pilot

- Brings together conformity assessment bodies, FDA and medical device industry
- Leverages international consensus standards
- Advances regulatory science

***ASCA Goal: Enhance the use of conformity assessment  
in premarket review***

# Summary

## The ASCA Pilot

- Increases consistency and predictability in assessing conformance with FDA-recognized standards
- Reduces regulatory burden by streamlining conformity assessment
- Ensures patient access to safe, effective devices



# Summary

- **Five steps to prepare a submission with ASCA testing**
  1. Identify the standard(s)
  2. Agree on test plan
  3. Plan submission elements
  4. Obtain results and Summary Test Reports
  5. Prepare FDA submission
  
- **Three elements of an ASCA submission**
  1. Cover letter with ASCA-specific information
  2. Declaration of Conformity
  3. Summary Test Reports

# ASCA Pilot Guidances

- **ASCA Pilot program guidance:** [The Accreditation Scheme for Conformity Assessment \(ASCA\) Pilot Program - Final Guidance](#)
- **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 \(ASCA\) Pilot Program](#)
- **Biocompatibility standards-specific guidance:** [Biocompatibility Testing of Medical Devices- Standards Specific Information for the Accreditation Scheme for Conformity Assessment \(ASCA\) Pilot Program](#)

# Website Resources

- **ASCA Pilot Web page**

[www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca](http://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca)

- **Standards & Conformity Assessment Program**

[www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#intro](http://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#intro)

- **FDA Recognized Consensus Standards Database**

[www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm)

# Standards Resources

- Recognition and Withdrawal of Voluntary Consensus Standards, final guidance***  
[www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards)
- Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices, final guidance***  
[www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices)
- CDRH Learn: How to Study and Market Your Device: Standards**  
[www.fda.gov/training/cdrhlearn/default.htm](http://www.fda.gov/training/cdrhlearn/default.htm)

# Industry Education: Three Resources for You

## 1. CDRH Learn: Multi-Media Industry Education

- Over 200 modules
- Videos, audio recordings, power point presentations, software-based “how to” modules
- Mobile-friendly: access CDRH Learn on your portable devices

[www.fda.gov/CDRHLearn](http://www.fda.gov/CDRHLearn)

## 2. Device Advice: Text-Based Education

- Comprehensive regulatory information on premarket and postmarket topics

[www.fda.gov/DeviceAdvice](http://www.fda.gov/DeviceAdvice)

## 3. Division of Industry and Consumer Education (DICE)

- Contact DICE if you have a question
- Email: [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)
- Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
- Web: [www.fda.gov/DICE](http://www.fda.gov/DICE)

# Your Call to Action

- Promote the use of recognized standards in device submissions
- Participate in the ASCA Pilot
- Email us at [ASCA@FDA.HHS.GOV](mailto:ASCA@FDA.HHS.GOV)
- Participate in standards development!

