Streamlining Conformity Assessment with FDA's ASCA Program

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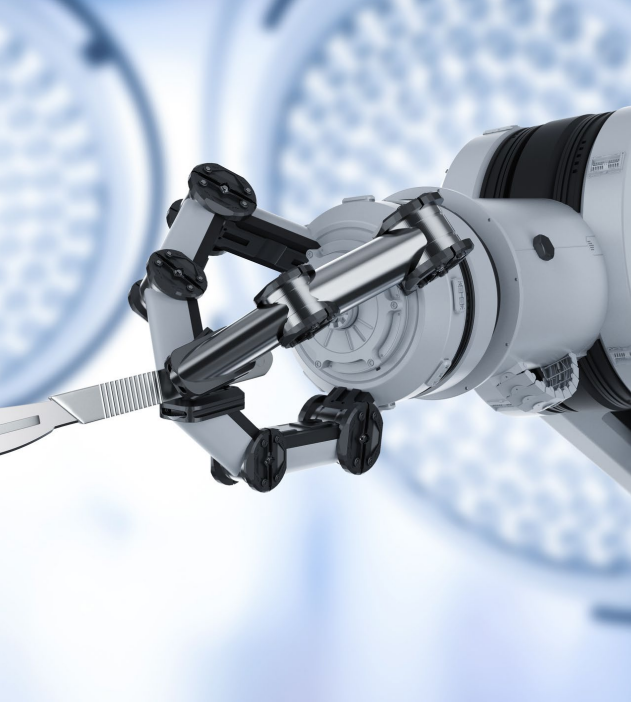


Topics

- The Accreditation Scheme for Conformity Assessment (ASCA)
- Benefits of participating in ASCA
- Real-world examples of ASCA testing
- Citing ASCA testing in device submissions
- Question and answer session

THE ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA)

What is ASCA?

- Capitalizes on FDA-recognized voluntary consensus standards in device development and review
- ‘Puts standards to work’ in conformity assessment
- *ASCA Accreditation* from FDA to qualified test labs means:
  - Confidence in their methods and results
  - No need for complete test report review

ISO/IEC 17011:2017
Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies

← Popular standards

ISO/IEC 17025
Testing and calibration laboratories

ASCA Standards: Biocompatibility

- Majority of medical devices need biocompatibility assessment
- ASCA includes the nine most common biocompatibility test methods
- Nine ASCA Summary Test Report templates are available

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 10993-23*	In Vivo Dermal Irritation, Intracutaneous Reactivity Irritation
ISO 10993-10*	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

**ISO 10993-10:2010 split into ISO 10993-10:2021 and ISO 10993-23:2021.*

**ISO 10993-10:2010, ISO 10993-10:2021, and ISO 10993-23:2021 are all included in ASCA.*

ASCA Standards:
Basic Safety and Essential Performance

- 82 standards
- Broad utilization across all medical electrical devices
- One ASCA Summary Test Report template

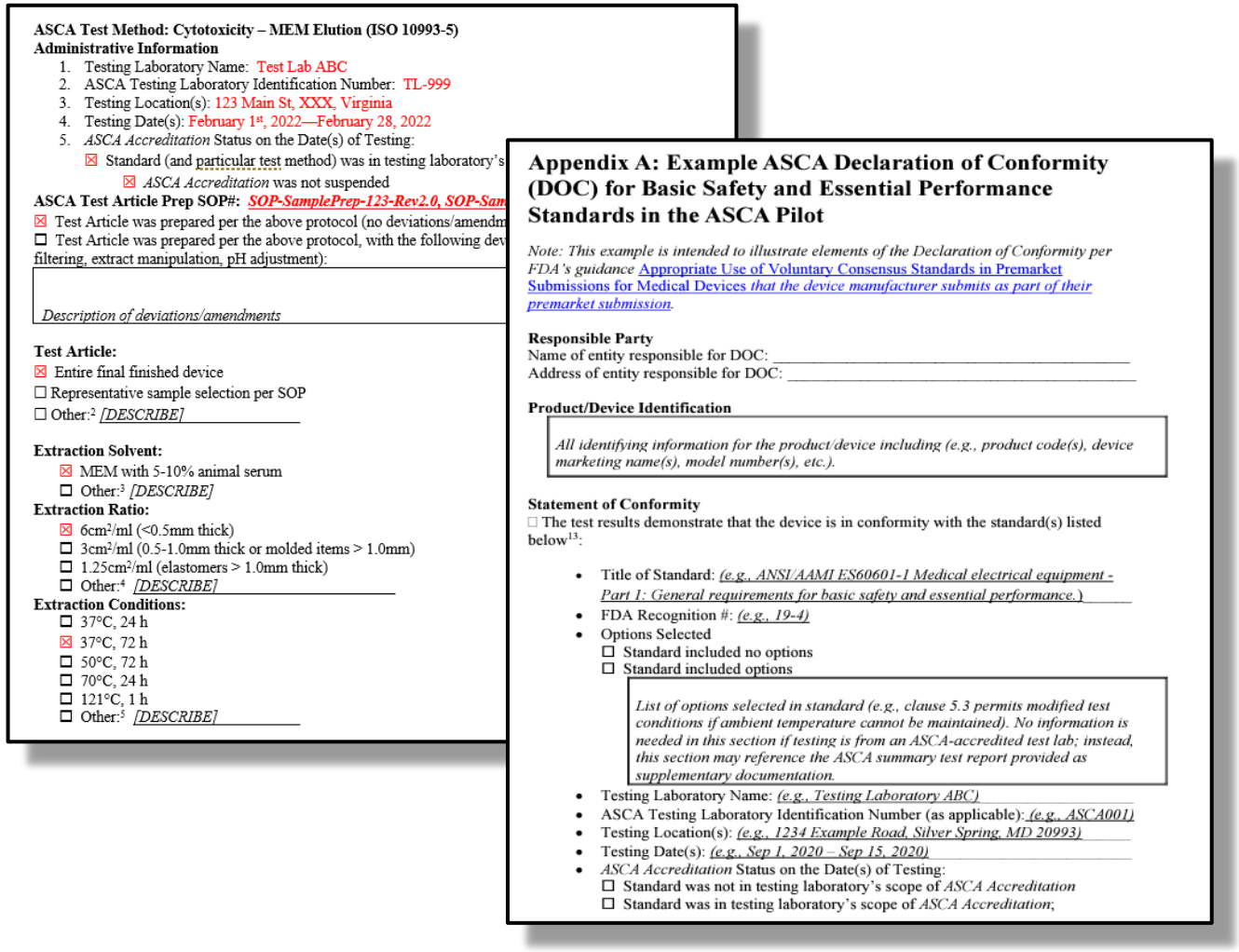
Standard	Standard Title
IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (along with the FDA-recognized collateral and particular standards in the IEC/ISO 60601-80601 series)
IEC 61010-1	Safety requirements for electrical equipment for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

BENEFITS OF PARTICIPATING IN ASCA

ASCA Goal: Streamline Conformity Assessment in Pre-market Review

Benefits of ASCA:

- Removes the guesswork about supporting documentation needs
- Provides templates for the only documentation needed:
  - — ASCA Declaration of Conformity
  - — ASCA Summary Test Report



ASCA Test Method: Cytotoxicity – MEM Elution (ISO 10993-5)
Administrative Information

1. Testing Laboratory Name: Test Lab ABC
2. ASCA Testing Laboratory Identification Number: TL-999
3. Testing Location(s): 123 Main St, XXX, Virginia
4. Testing Date(s): February 1st, 2022—February 28, 2022
5. *ASCA Accreditation* Status on the Date(s) of Testing:
   - ☒ Standard (and particular test method) was in testing laboratory's
   - ☒ *ASCA Accreditation* was not suspended

ASCA Test Article Prep SOP#: ***SOP-SamplePrep-123-Rev2.0, SOP-Sam***

☒ Test Article was prepared per the above protocol (no deviations/amendm
☐ Test Article was prepared per the above protocol, with the following dev
filtering, extract manipulation, pH adjustment):

Description of deviations/amendments

Test Article:
☒ Entire final finished device
☐ Representative sample selection per SOP
☐ Other:[2] *[DESCRIBE]*

Extraction Solvent:
☒ MEM with 5-10% animal serum
☐ Other:[3] *[DESCRIBE]*

Extraction Ratio:
☒ 6cm²/ml (<0.5mm thick)
☐ 3cm²/ml (0.5-1.0mm thick or molded items > 1.0mm)
☐ 1.25cm²/ml (elastomers > 1.0mm thick)
☐ Other:[4] *[DESCRIBE]*

Extraction Conditions:
☐ 37°C, 24 h
☒ 37°C, 72 h
☐ 50°C, 72 h
☐ 70°C, 24 h
☐ 121°C, 1 h
☐ Other:[5] *[DESCRIBE]*

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.

Responsible Party
Name of entity responsible for DOC: _____
Address of entity responsible for DOC: _____

Product/Device Identification

All identifying information for the product/device including (e.g., product code(s), device marketing name(s), model number(s), etc.).

Statement of Conformity
☐ The test results demonstrate that the device is in conformity with the standard(s) listed below[13]:

- Title of Standard: *(e.g., ANSI/AAMI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.)*
- FDA Recognition #: *(e.g., 19-4)*
- Options Selected
  - ☐ Standard included no options
  - ☐ Standard included options

  List of options selected in standard (e.g., clause 5.3 permits modified test conditions if ambient temperature cannot be maintained). No information is needed in this section if testing is from an ASCA-accredited test lab; instead, this section may reference the ASCA summary test report provided as supplementary documentation.
- Testing Laboratory Name: *(e.g., Testing Laboratory ABC)*
- ASCA Testing Laboratory Identification Number (as applicable): *(e.g., ASCA001)*
- Testing Location(s): *(e.g., 1234 Example Road, Silver Spring, MD 20993)*
- Testing Date(s): *(e.g., Sep 1, 2020 – Sep 15, 2020)*
- *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 Benefits, continued

- Reduces time needed for the conformity assessment element of device review
- Less need for Additional Information questions, lengthy internal consults and complete test report review
- Improves the quality of testing and reporting
  - Addresses testing issues for which FDA commonly identifies concerns

IEC 60601-1-2 Review: ASCA vs. Non-ASCA

- IEC 60601-1-2: complete test reports include images of the test set-up
  - Poor or unclear test set-ups, could raise deficiencies (see example below):

    In your electromagnetic compatibility (EMC) report, you stated that the testing is done on the x, y, and z-axes. However, in your test setup, you have shown the horizontal plane is improperly oriented and has a coil size smaller than the full equipment under test (EUT). This standard is intended to demonstrate common and reproducible basis for evaluating the performance of your device applications when subjected to magnetic fields at power frequency. The processing unit of the device should be exposed during testing. We request that you clarify how the EUT was exposed to x, y, and z axes given the demonstrated test setup. If the processing system was not adequately exposed, we request that you perform new testing demonstrating the device is safe when subjected to magnetic fields at power frequency.

- Using ASCA, we have confidence in ASCA-accredited labs' methods and results
  - No deficiencies would be identified for testing methodology/set-up

REAL-WORLD EXAMPLES OF ASCA TESTING

Real World Example: non-ASCA vs. ASCA Testing

Class II Device	Non-ASCA Testing (IEC 60601-1-2)	ASCA Testing (ANSI/AAMI ES60601-1)
Deficiencies	1 major 3 minor	0
Length of report	46 pages	9 pages

Real World Example: non-ASCA vs. ASCA Testing

Class II Device	Non-ASCA Testing (60601-1 + 60601-2-2)	ASCA Testing (60601-1 + 60601-2-2)
Deficiencies	1 major	0
Length of report	203 pages	4 pages

ASCA Wound Therapy Device Submission: Basic Safety and Essential Performance Assessment

- Negative Pressure Wound Therapy Powered Suction Pump
  - device that promotes wound healing by the removal of excess exudates, infectious material, and tissue debris

- Basic Safety and Essential Performance ASCA testing:
  - IEC 60601-1
  - IEC 60601-1-2
  - IEC 60601-1-6
  - IEC 60601-1-8
  - IEC 60601-1-11

ASCA Wound Therapy Device Submission: Basic Safety and Essential Performance Review

60601-1 and all collaterals	Complete Test Reports (provided alongside ASCA Summary Test Reports)	ASCA Testing: ASCA Summary Test Reports
Review staff		No need for consult
Page count	407 pages total	20 pages total
Estimate of review time	~ 10 hours	~ 1 hours
Deficiencies identified		0

ASCA Lancet Submission: Biocompatibility Assessment

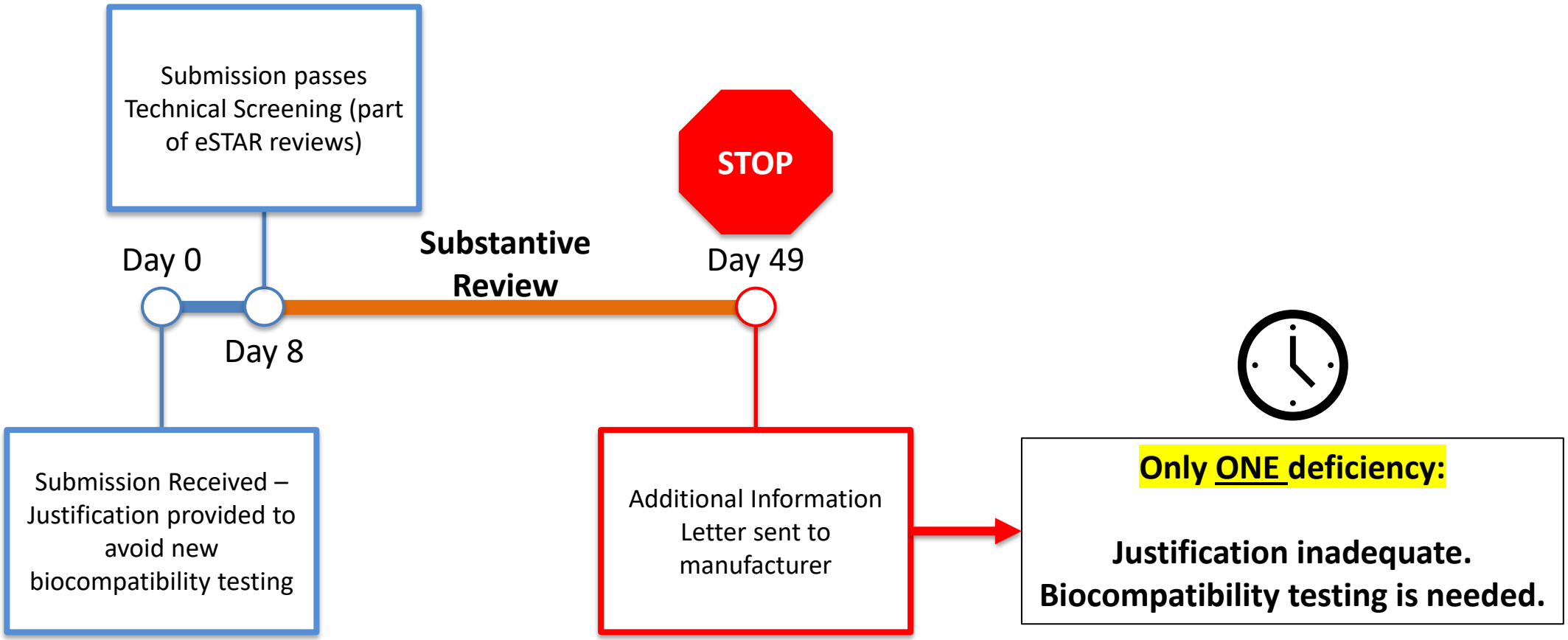
Contact type

- Limited skin-contacting devices (<24 h)

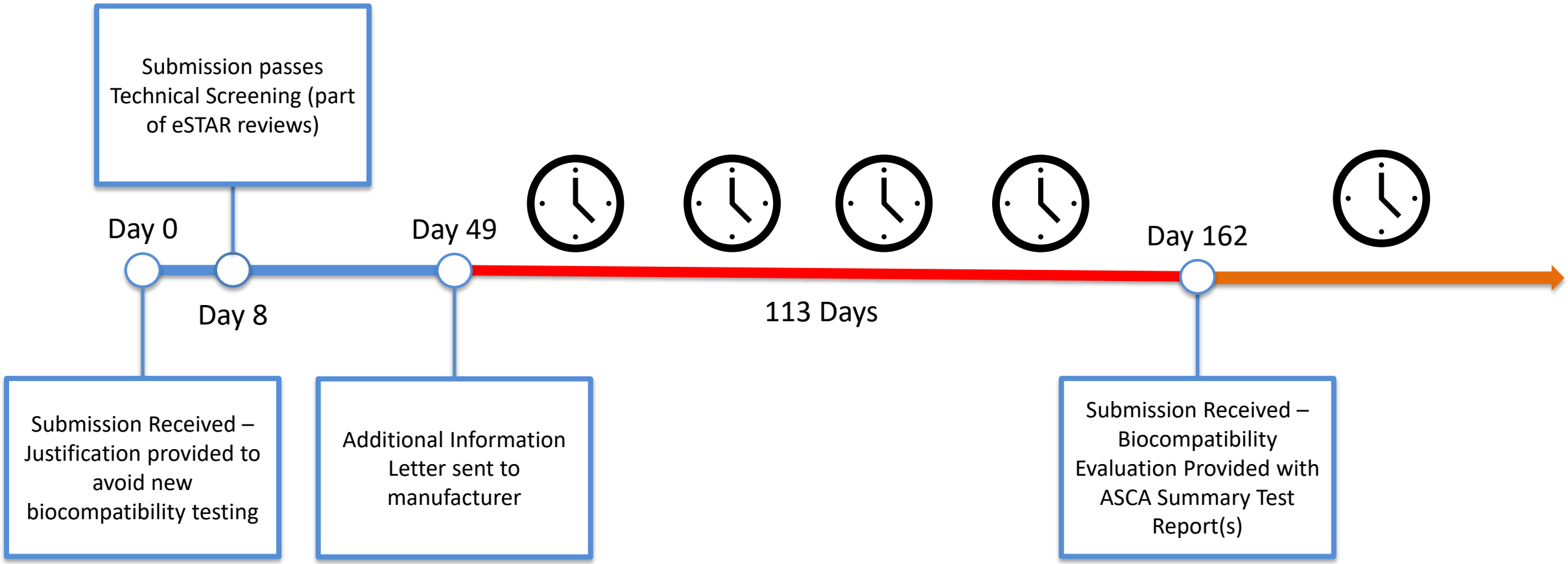
ASCA Biocompatibility Assessment

- Intracutaneous Reactivity Irritation
- Guinea Pig Maximization Sensitization
- MEM Elution Cytotoxicity

ASCA Submission: Biocompatibility



ASCA Submission: Biocompatibility



Example ASCA Summary Test Report: Cytotoxicity

ASCA Test Method: Cytotoxicity – MEM Elution (ISO 10993-5)
Administrative Information

1. Testing Laboratory Name: Test Lab ABC
2. ASCA Testing Laboratory Identification Number: TL-999
3. Testing Location(s): 123 Main St, XXX, Virginia
4. Testing Date(s): February 1st, 2022—February 28, 2022
5. *ASCA Accreditation* Status on the Date(s) of Testing:
   - ☒ Standard (and particular test method) was in testing laboratory's scope of *ASCA Accreditation*
   - ☒ *ASCA Accreditation* was not suspended

ASCA Test Article Prep SOP#: *SOP-SamplePrep-123-Rev2.0, SOP-SampleExtr-456-Rev3.0*

☒ Test Article was prepared per the above protocol (no deviations/a
☐ Test Article was prepared per the above protocol, with the follow
filtering, extract manipulation, pH adjustment):

Description of deviations/amendments

Test Article:
☒ Entire final finished device
☐ Representative sample selection per SOP
☐ Other:[2] *[DESCRIBE]*

Extraction Solvent:
☒ MEM with 5-10% animal serum
☐ Other:[3] *[DESCRIBE]*

Extraction Ratio:
☒ 6cm²/ml (<0.5mm thick)
☐ 3cm²/ml (0.5-1.0mm thick or molded items > 1.0mm)
☐ 1.25cm²/ml (elastomers > 1.0mm thick)
☐ Other:[4] *[DESCRIBE]*

Extraction Conditions:
☐ 37°C, 24 h
☒ 37°C, 72 h
☐ 50°C, 72 h
☐ 70°C, 24 h
☐ 121°C, 1 h
☐ Other:[5] *[DESCRIBE]*

8 pages
20-40 minutes

☒ The test article and extract DID NOT change color, and the extract DID NOT appear turbid or have particles.
☐ There were changes in color/turbidity or particles in the test article and/or extract OR there was swelling/degradation of the test article.[5]

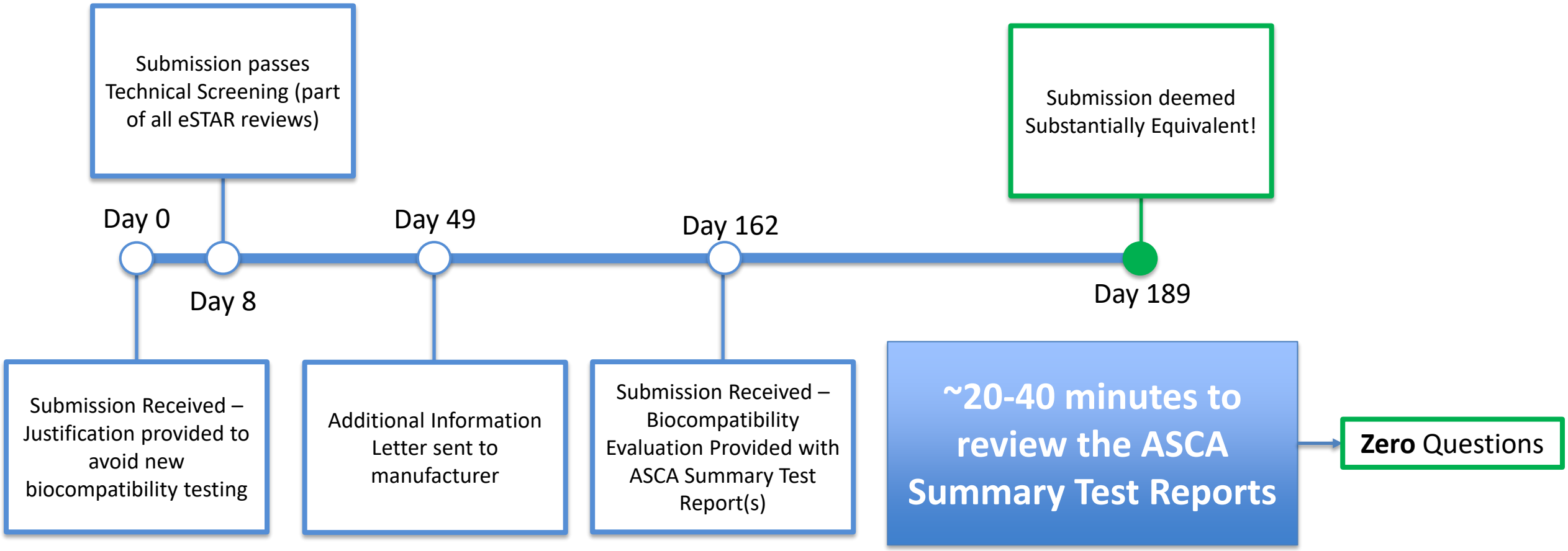
ASCA Test Method SOP #: *SOP-ASCA-MEM-789-Rev2.0*
☒ Test was conducted per the above protocol (no deviations/amendments) and 21 CFR 58; or
☐ Test was conducted per the above protocol and 21 CFR 58, with the following deviations/amendments:[6]

	hr ults	72 hr Results	Conclusion
	ade /0	Grade 0/0/0	Performed as expected
	ade /0	Grade 0/0/0	Performed as expected
	ade /4	Grade 4/4/4	Performed as expected
Test Article Extract (100% neat)	Grade 0/0/0	Grade 0/0/0	Non-cytotoxic

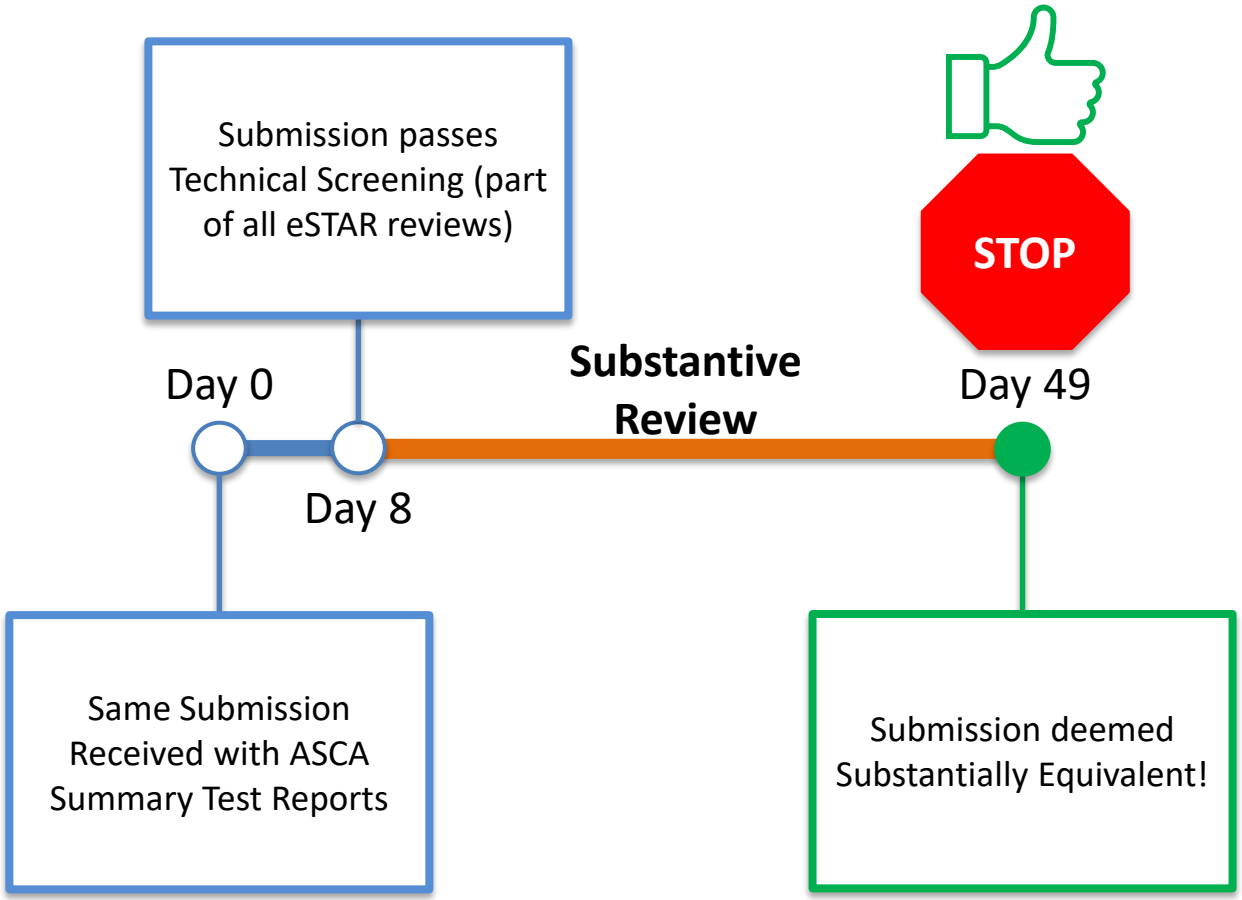
I confirm that:
☒ The above summary information includes all original and any retest data; and
☒ I have checked that there are no differences between the complete test report and this ASCA summary test report.

John Standards — 3/15/2022
Name: [TYPED NAME POSITION] — Date

ASCA Submission: Biocompatibility



ASCA Submission: Biocompatibility

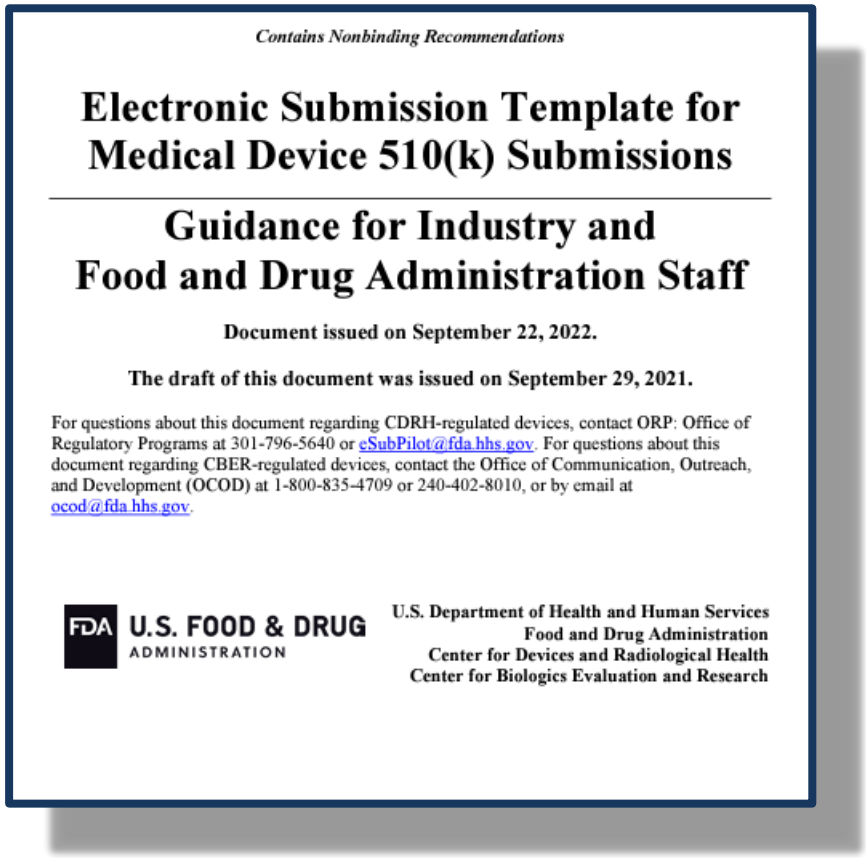


	Biocompatibility Justification at Day 0	Using ASCA Testing from Day 0
Deficiencies	1 major	0
FDA Days	76	~49 (or less)
Total Days after Day 0	189	~49 (or less)

CITING ASCA TESTING IN DEVICE SUBMISSIONS

ASCA Submission Elements

Cover Letter	• States that submission has ASCA testing • Name, location and IDs of test lab(s) • FDA-recognized consensus standard(s) and test methods used
ASCA Declaration of Conformity (DOC)	• Manufacturer provides the DOC • *ASCA Accreditation* status for the test lab • Please use example DOCs in ASCA guidances
ASCA Summary Test Report	• See standards-specific ASCA guidance documents for examples



Contains Nonbinding Recommendations

Electronic Submission Template for Medical Device 510(k) Submissions

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 22, 2022.

The draft of this document was issued on September 29, 2021.

For questions about this document regarding CDRH-regulated devices, contact ORP: Office of Regulatory Programs at 301-796-5640 or eSubPilot@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

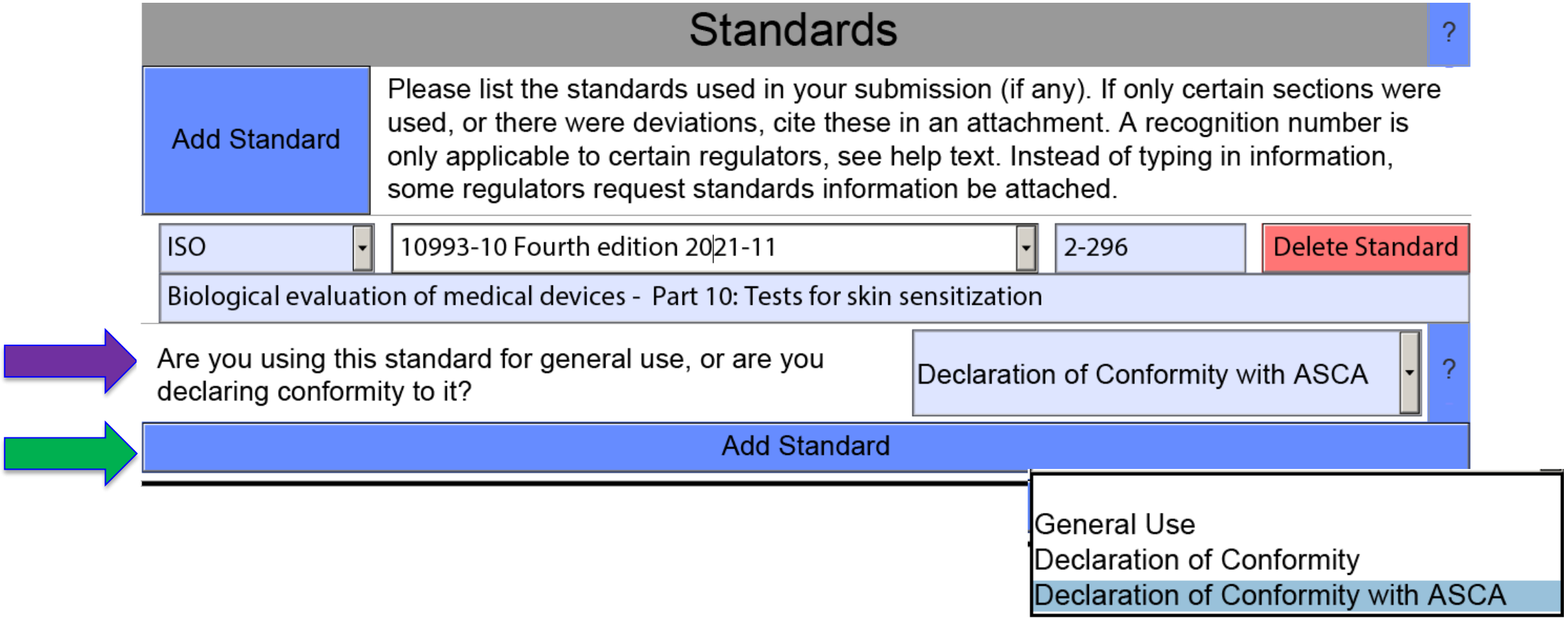
What is eSTAR?

- A dynamic PDF submission template for medical device submissions
- Features automation, guides, integrated databases, policies and procedures
- Guides applicant step by step through the device submission process

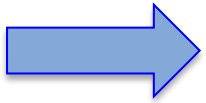
Two templates

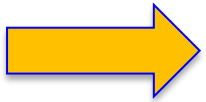
- nIVD and IVD
- Available at: *https://www.fda.gov/medical-devices/premarket-notification-510k/voluntary-estar-program*

Documenting Standards in eSTAR



Documenting Standards in eSTAR: DOC





Declaration of Conformity

Application # 1200

Company Name	Diamond Device Company
Company Address	10 Main Street Technopolis VA 99999 United States
Device Trade Name	Gemstone Device

The subject device(s) is in conformity with the requirements of the following documents:

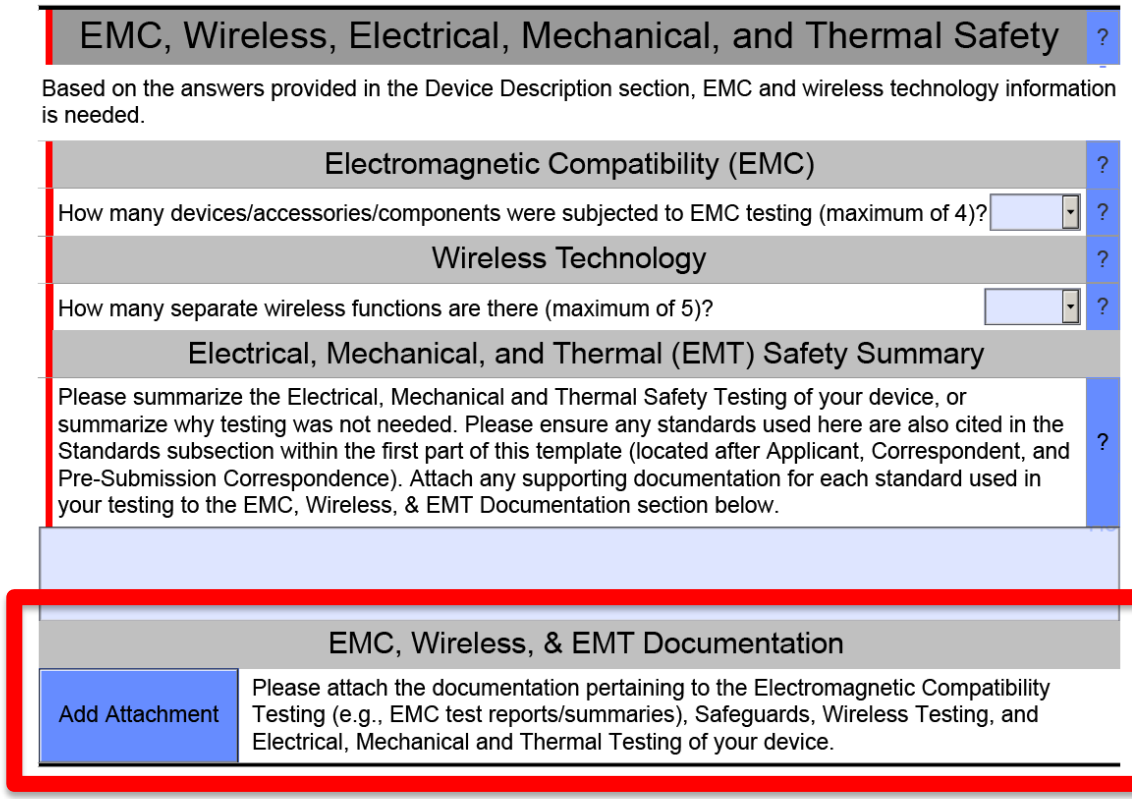
Organization	Designation Number and Edition/Date	Recognition #
ISO	10993-10 Fourth edition 2021-11	2-296

Additional Information (e.g., limitations on the validity of the Declaration of Conformity)

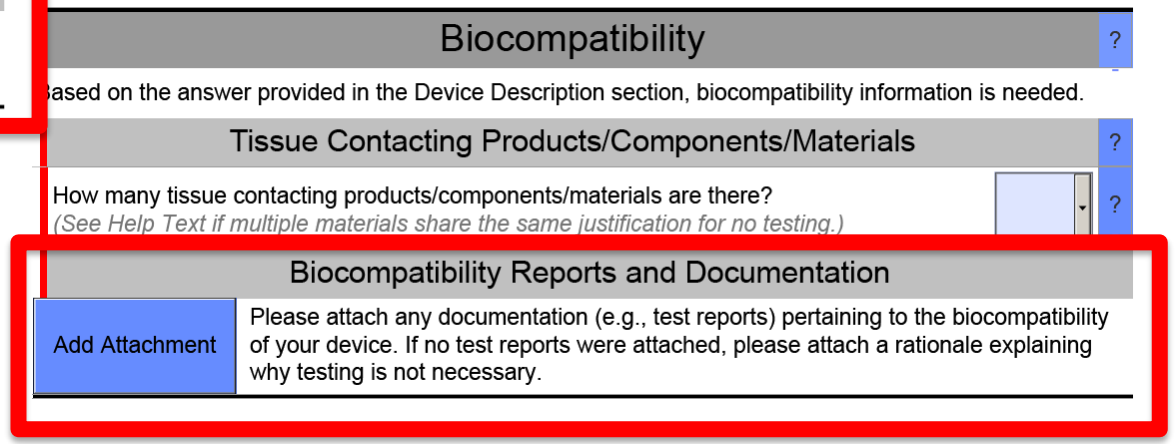
Signed for and on behalf of the applicant company:

Place and Issuance Date:	Technolopolis, VA, USA	February 1, 2024
Full Name and Title:	Mr. Regulatory Professional	
Signature	*Regulatory Professional*	

Documenting ASCA Standards in eSTAR - Attachments



** Attach the ASCA Summary Test Reports to the relevant
eSTAR sections **



ASCA By the Numbers

93 Standards included in ASCA	**113** Submissions highlighting ASCA	**107** ASCA-accredited testing laboratories
316 Standards tested in ASCA Summary Test Reports	**97** Submissions with ASCA Summary Test Report	**97%** ASCA submissions for which FDA requested no complete test reports

Future

- ASCA is a permanent Program
- Draft Guidances out for comment
  - Link to Docket
- ASCA Expansion workshop held on April 17, 2024
  - Link to Workshop

Future

- ASCA Workshop on Potential Inclusion of Chemical Characterization Biocompatibility Method
  - November 6, 2024
  - Register here

FDA Industry Updates and Education

1. **CDRH New**
   - Sign up at: https://public.govdelivery.com/accounts/USFDA/subscribers/qualify
2. **CDRH Learn: Multi-Media Industry Education**
   - Videos, audio recordings, power point presentations, software-based "how to" modules
   - www.fda.gov/CDRHLearn
3. **Device Advice: Text-Based Education**
   - Comprehensive regulatory information on premarket and postmarket topics
   - www.fda.gov/DeviceAdvice
4. **Division of Industry and Consumer Education (DICE)**
   - Email: 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
5. **eSTAR Program**
   - https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program?utm_medium=email&utm_source=govdelivery
   - eSTAR Assistance: 510K_Program@fda.hhs.gov
   - Tech Questions/Feedback: eSubpilot@fda.hhs.gov

FDA Standards Resources

- **Division of Standards and Conformity Assessment (DSCA)**
  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
- **Non-recognized Standards Database**
  https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/nr_results.cfm
- **Email us at: CDRHStandardsStaff@fda.hhs.gov**

Relevant FDA Guidances

- **Recognition and Withdrawal of Voluntary Consensus Standards guidance**
  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 guidance**
  www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

- **Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff**
  https://www.fda.gov/media/113230/download

ASCA Resources

- **ASCA web page**
  www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca
- **ASCA program guidance**
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program
- **ASCA Standards-specific guidances**
  - **Basic Safety and Essential Performance standards-specific guidance:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and
  - **Biocompatibility standards-specific guidance:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme
- **Ask ASCA! ASCA@FDA.HHS.GOV**

ASCA Draft Guidances

- **Draft ASCA Program Guidance:**
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-program

- **Draft ASCA Biocompatibility Guidance:**
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme-0

- **Draft ASCA Basic Safety and EP Guidance:**
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and-0

- **Docket for Commenting:**
  https://www.regulations.gov/docket/FDA-2019-D-3805/document

QUESTIONS


FDA
U.S. FOOD & DRUG
ADMINISTRATION