# The eSTAR and I

## Getting to Know the eSTAR Templates for FDA Submissions


**PRESENTERS**

- **Lisa Pritchard**, VP, Regulatory, Quality, Clinical & Engineering, DuVal & Associates, P.A.
- **Kathy Herzog**, Sr Regulatory, Quality & Compliance Consultant, DuVal & Associates, P.A.
- **Patrick Axtell**, Assistant Director, Tools and Templates Team, US Food and Drug Administration

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# Learning Objectives

- Understand how the eSTAR templates are designed, their content requirements, and how to use the built-in help features
- Know how to prepare an eSTAR 510(k), De Novo, or PreSub
- Understand how to manage submission updates during the review process

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# Agenda

- Act I : Getting to Know You
  - Overview of eSTAR program
- Act II: Getting to Know All About You
  - Use of eSTAR templates
- Act III: Getting to Like You
  - Strategies for Completion and Best Practices for Optimizing eSTAR submission presentation
- Act IV: Getting to Hope You Like Me
  - FDA Review Process, responding to deficiencies, eSTAR program plans
- Summary / Q&A

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# Act I : Getting to Know You

## Overview of eSTAR Program

Patrick Axtell, Ph.D.
US Food and Drug Administration

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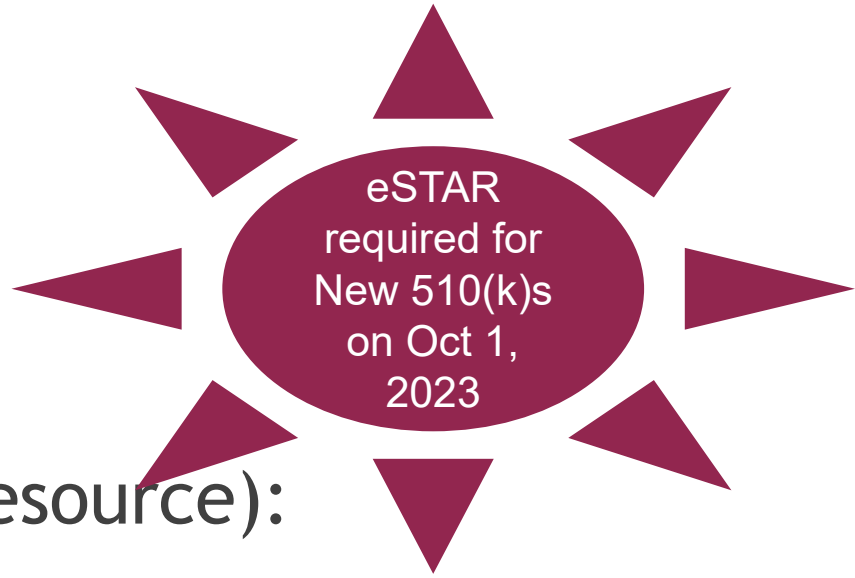



# What is eSTAR?

- eSTAR (electronic Submission Template And Resource):
  - Interactive PDF forms for 510(k), De Novo, and PreSub submissions to CDRH
  - Aligns with content and structure with CDRH internal review templates
  - Guides submitters through the submission process with automation, guided construction for each section, integration with FDA's databases, built in forms (e.g. Form 3881, 3514), and automatic verification
  - Standardized eSTAR PDF submitted in place of unstandardized eCopy
  - No RTA review
  - Automatically verifies whether the eSTAR is complete

# Preparing an eSTAR Submission

Download eSTAR (it is the top hit when you Google “fda estar”):

- https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program

Right-click and download the eSTAR PDF

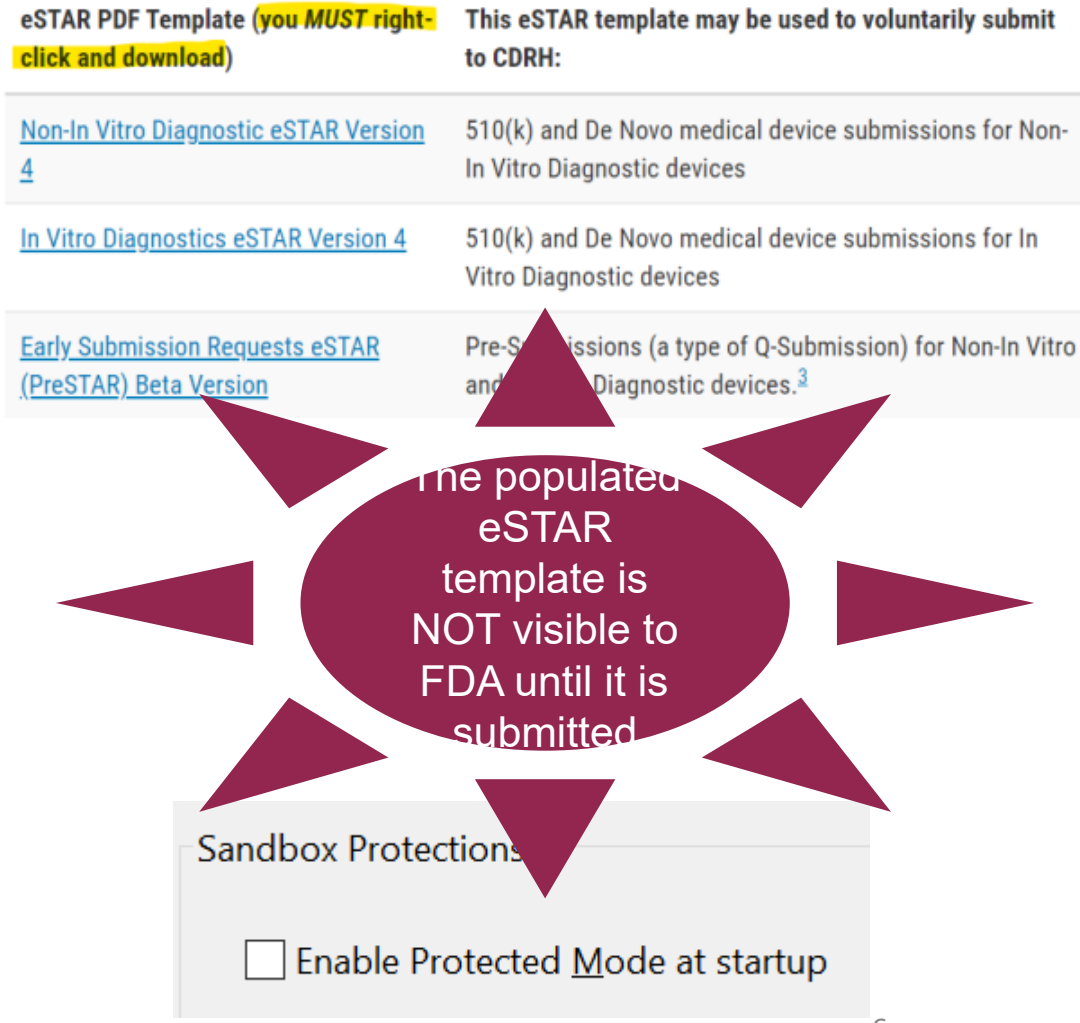
- Web browsers can’t open dynamic PDFs like Form 3514, the IFU form, and eSTAR
- Download correct form

Refer to Lili Duan’s YouTube presentation regarding eSTAR use

- https://www.youtube.com/watch?v=9t74xtVNoDw&t=18140s
- Use the CDRH Portal instead: https://ccp-aws.fda.gov/

Windows Adobe Acrobat Pro slowness bug:

- Uncheck the checkbox under: Edit → Preferences → Security (Enhanced) → Enable Protected Mode at startup
- Contact DICE@fda.hhs.gov if you still encounter slowness



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FAQ: Questions about attachments answered here

Changes: You are not forced to use latest eSTAR

## FAQ

Q: Where can I send questions, feedback, and/or bug reports?
A: For technical issues or bug reports please email eSubPilot@fda.hhs.gov.
For regulatory process or content questions please email:
USFDA: DICE@fda.hhs.gov
Health Canada: meddevices-instrumentsmed@hc-sc.gc.ca

Q: When I click on a bookmark, the view jumps to the beginning of eSTAR. Why did this happen?
A: The bookmarked section is not applicable based on your submission choices and therefore should be ignored.

Q: Is there an attachment type or size restriction?
A: eSTAR will prevent unacceptable attachment types from being added. If your eSTAR is greater than 1GB, file

## Version History

A major version update will consist of policy changes, regulatory changes, or major changes to the template and will be denoted by a major version number increment (e.g., 1.2 to 2.0). A minor version update will consist of other changes and will be denoted by a minor version number increment (e.g., 1.2 to 1.3). eSTARs updated with policy or regulatory changes will be made available before the implementation date of those changes, and the previous eSTAR will be removed on the implementation date. **Be sure you submit using the major version that is currently implemented, otherwise you may receive additional information requests related to the changes.**

Version History

2.2 (2023-01-10): FDA PMA and Health Canada content finalized, disabled for all but pilot participants.

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Application Jurisdiction currently locked except for pilot program participants

Will come back to this in Act IV

Selecting Application Purpose unlocks sections to be completed

Application Type further refines the application

Change Application Sub Type when responding to questions

## Application/Submission Type

| | |
|---|---|
| Application Jurisdiction | (•) US FDA<br>( ) Health Canada |

**If none of the attachments to a question are relevant to the question, or if an inaccurate response is provided to any question, the submission may be put on an early Technical Screening hold, which would request correction of these inadequacies.** Examples of responses that would place the submission on a Technical Screening hold include: stating "0" wireless functions are used, but wireless functions are used by the device, improperly indicating device(s) changes are appropriate for a Special 510(k), improper citation of attachments or page numbers in text boxes, stating "N/A" in text boxes that are applicable. An example of an irrelevant attachment includes providing attachments to the software description question none of which contains a software description. FDA may also put the submission on hold if an English translation for any documentation provided is not included.

The content of this template complements the FDA reviewer's smart template used in reviewing submissions, and therefore this template will provide the reviewers what they are expecting. This may reduce the number of inconsistencies and omissions in your application/submission documents, and therefore the number of additional information requests the FDA may send to you.

| | |
|---|---|
| Application Purpose | (•) Premarket Notification 510(k)<br>( ) De Novo<br>( ) Premarket Application PMA |

Show Application Introduction

| | |
|---|---|
| Application Type<br>*(Choose Abbreviated if you are submitting a Safety & Performance based submission.)* | (•) Traditional<br>( ) Abbreviated<br>( ) Special |

Show Application Type Introduction

| | |
|---|---|
| Application Sub-Type<br>*(Modify the Original eSTAR when responding to Additional Information requests. See Help Text)* | (•) New Application/Submission<br>( ) Additional Information |

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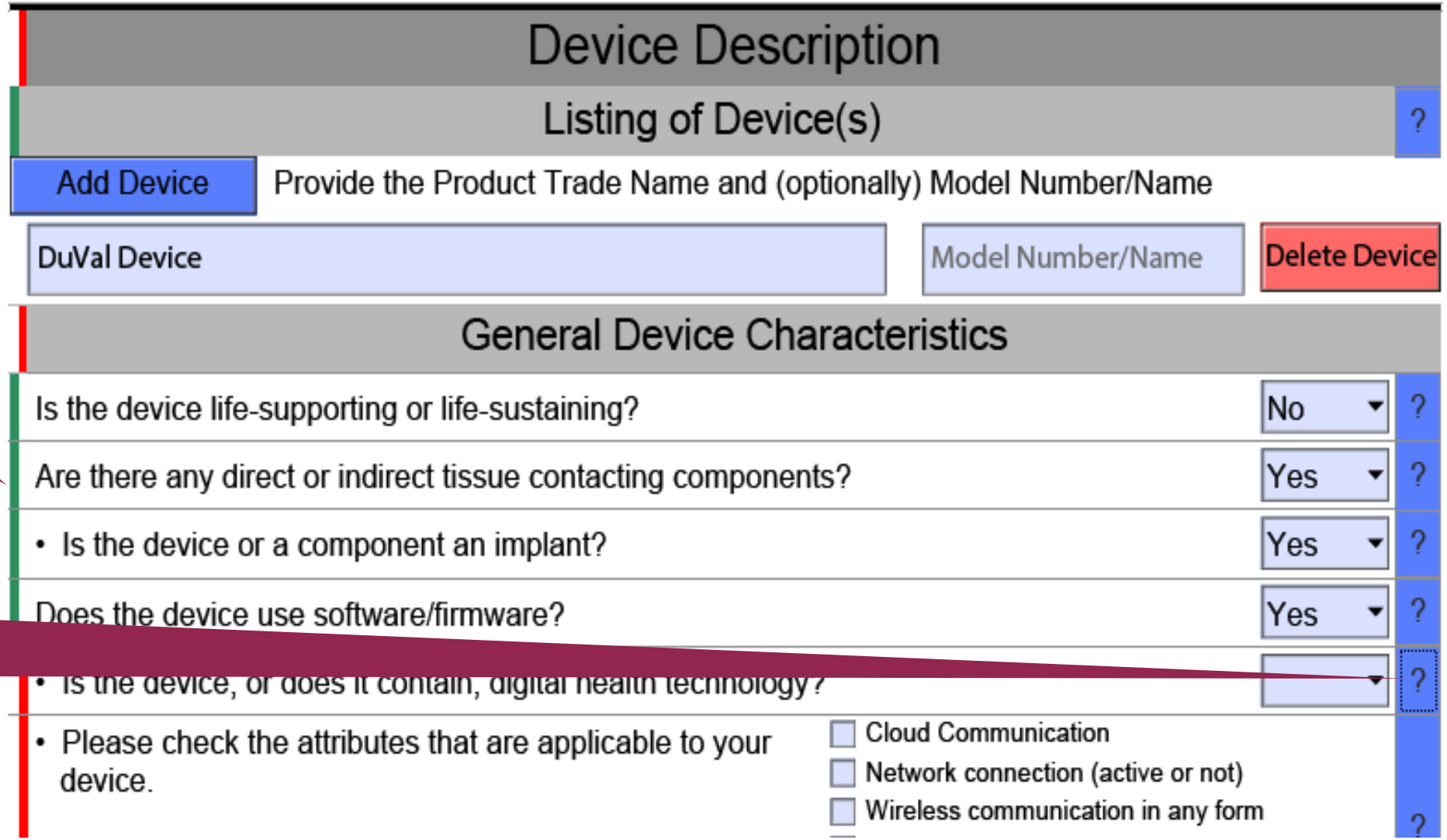
Red bar denotes information still needed

Green bar denotes information Complete

Blue Question Marks provide helpful information in a pop-up window



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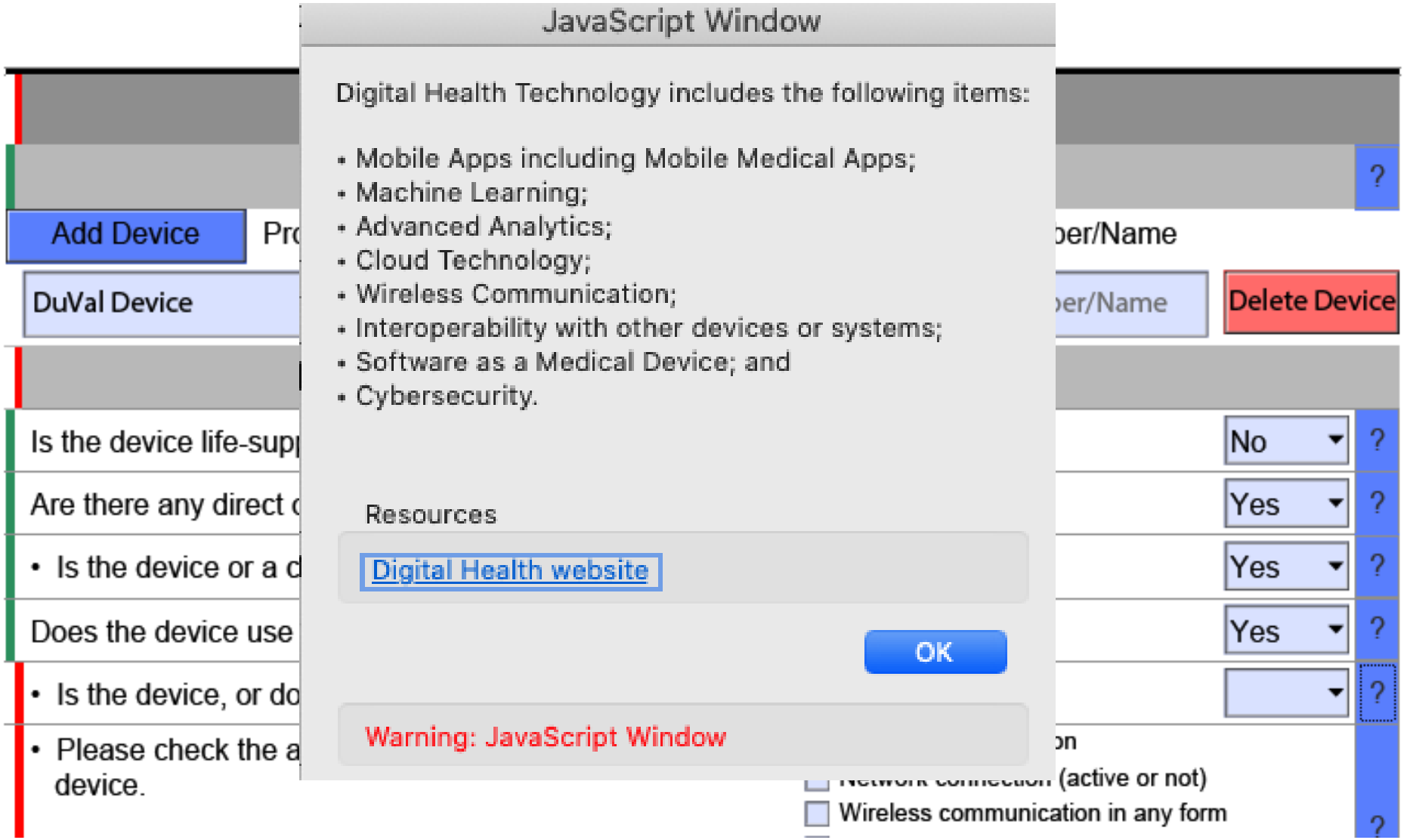

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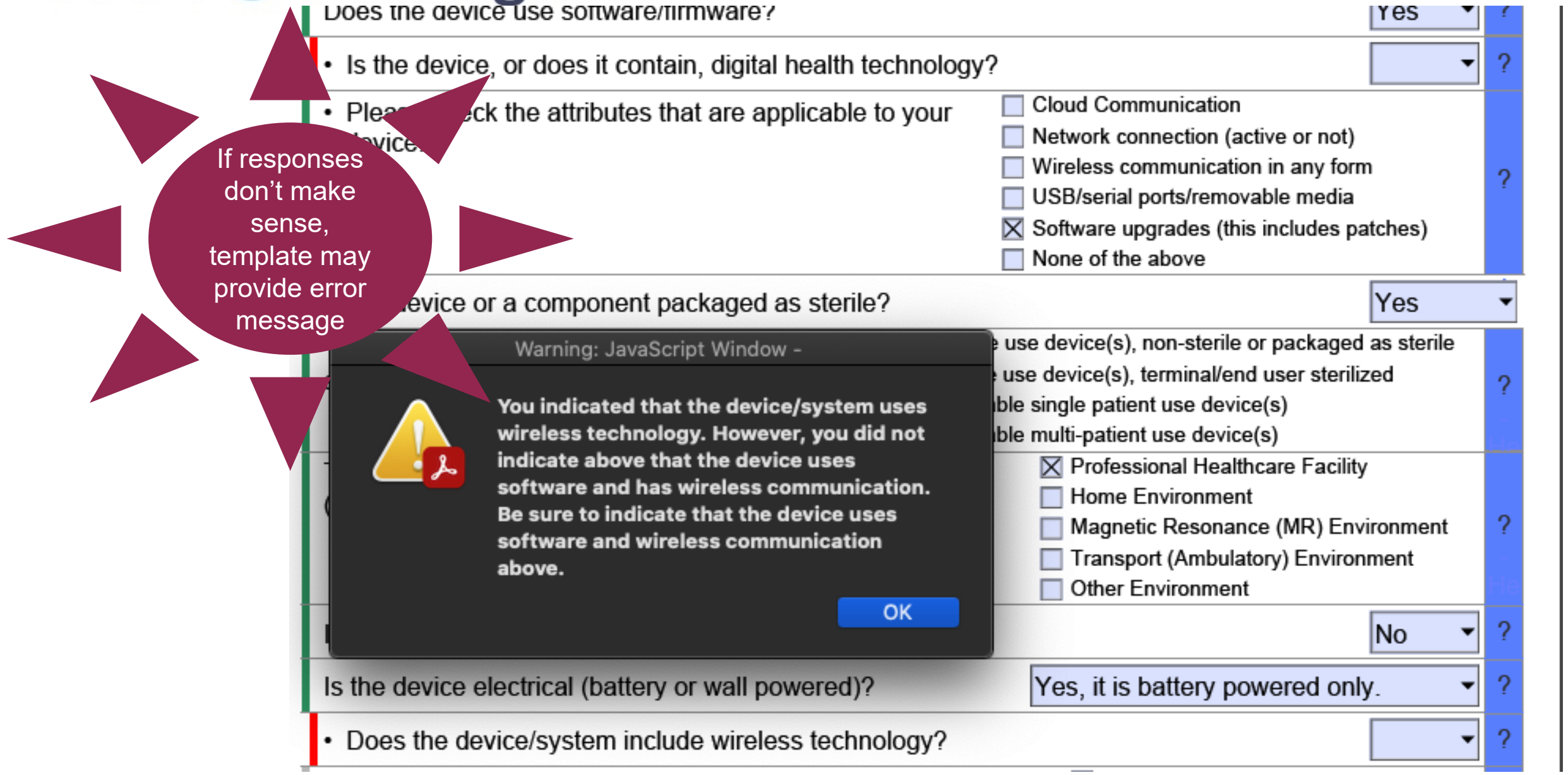


If responses don't make sense, template may provide error message

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# Act II: Getting to Know All About You

## Use of the eSTAR Templates

Kathy Herzog, BSME
DuVal & Associates, P.A.

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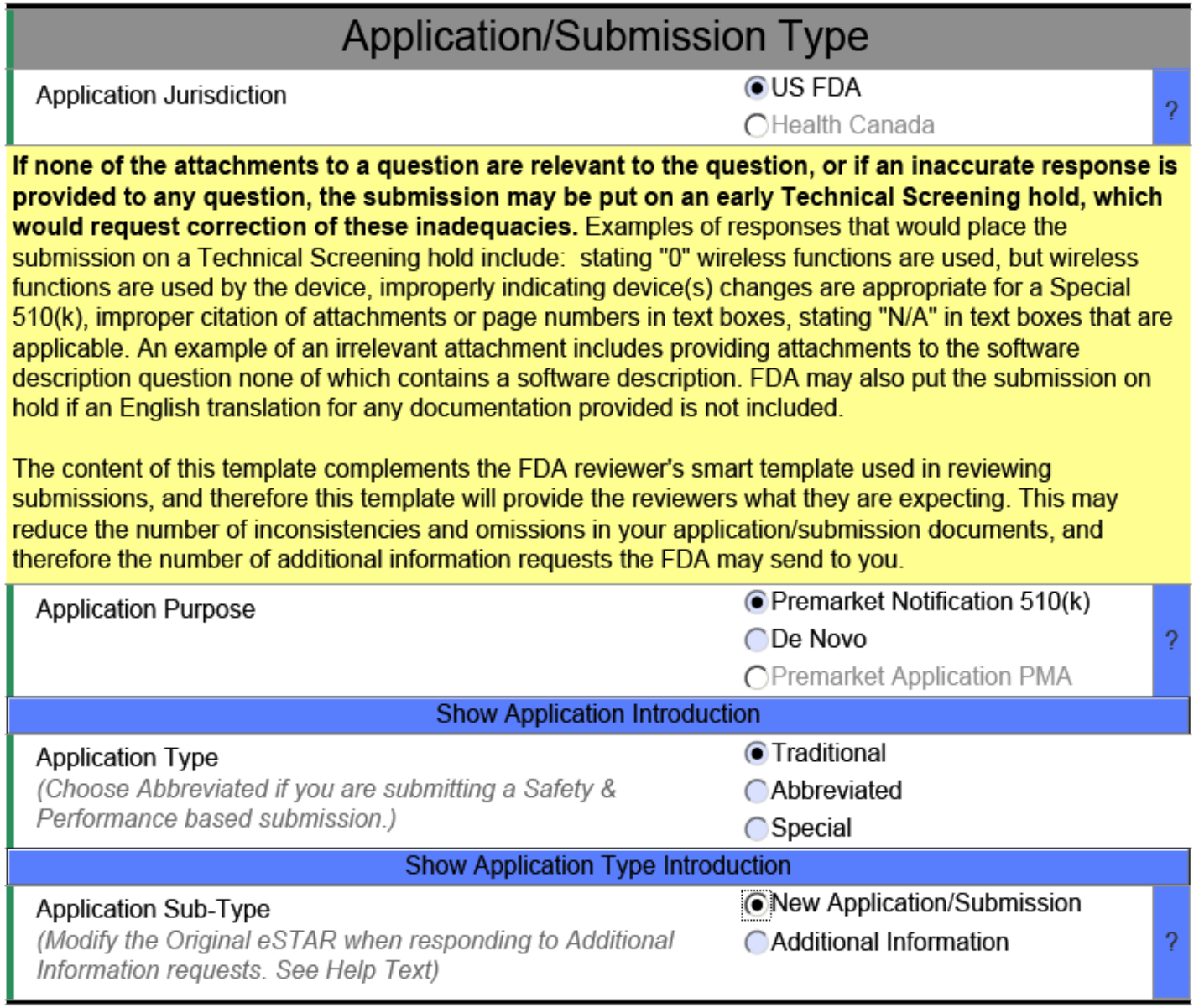
# Strategies for Completion – Radio Buttons

- Complete from beginning of template
- Utilize help text for clarity as needed
- When in doubt, try different options to test impact on available fields



**Application/Submission Type**

Application Jurisdiction
- (•) US FDA
- ( ) Health Canada

?

**If none of the attachments to a question are relevant to the question, or if an inaccurate response is provided to any question, the submission may be put on an early Technical Screening hold, which would request correction of these inadequacies.** Examples of responses that would place the submission on a Technical Screening hold include: stating "0" wireless functions are used, but wireless functions are used by the device, improperly indicating device(s) changes are appropriate for a Special 510(k), improper citation of attachments or page numbers in text boxes, stating "N/A" in text boxes that are applicable. An example of an irrelevant attachment includes providing attachments to the software description question none of which contains a software description. FDA may also put the submission on hold if an English translation for any documentation provided is not included.

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Application Purpose
- (•) Premarket Notification 510(k)
- ( ) De Novo
- ( ) Premarket Application PMA

?

Show Application Introduction

Application Type
*(Choose Abbreviated if you are submitting a Safety & Performance based submission.)*
- (•) Traditional
- ( ) Abbreviated
- ( ) Special

Show Application Type Introduction

Application Sub-Type
*(Modify the Original eSTAR when responding to Additional Information requests. See Help Text)*
- (•) New Application/Submission
- ( ) Additional Information

?

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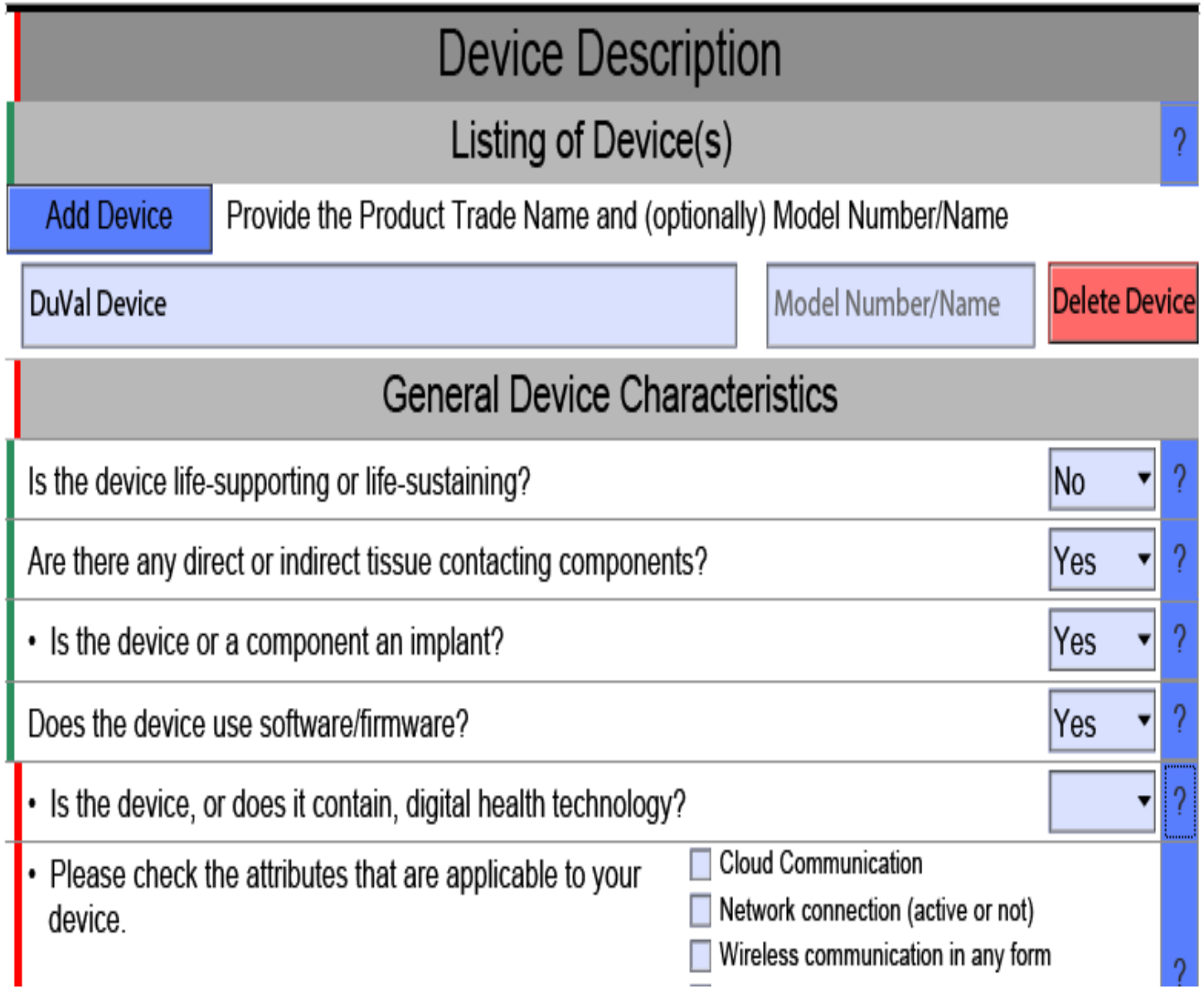
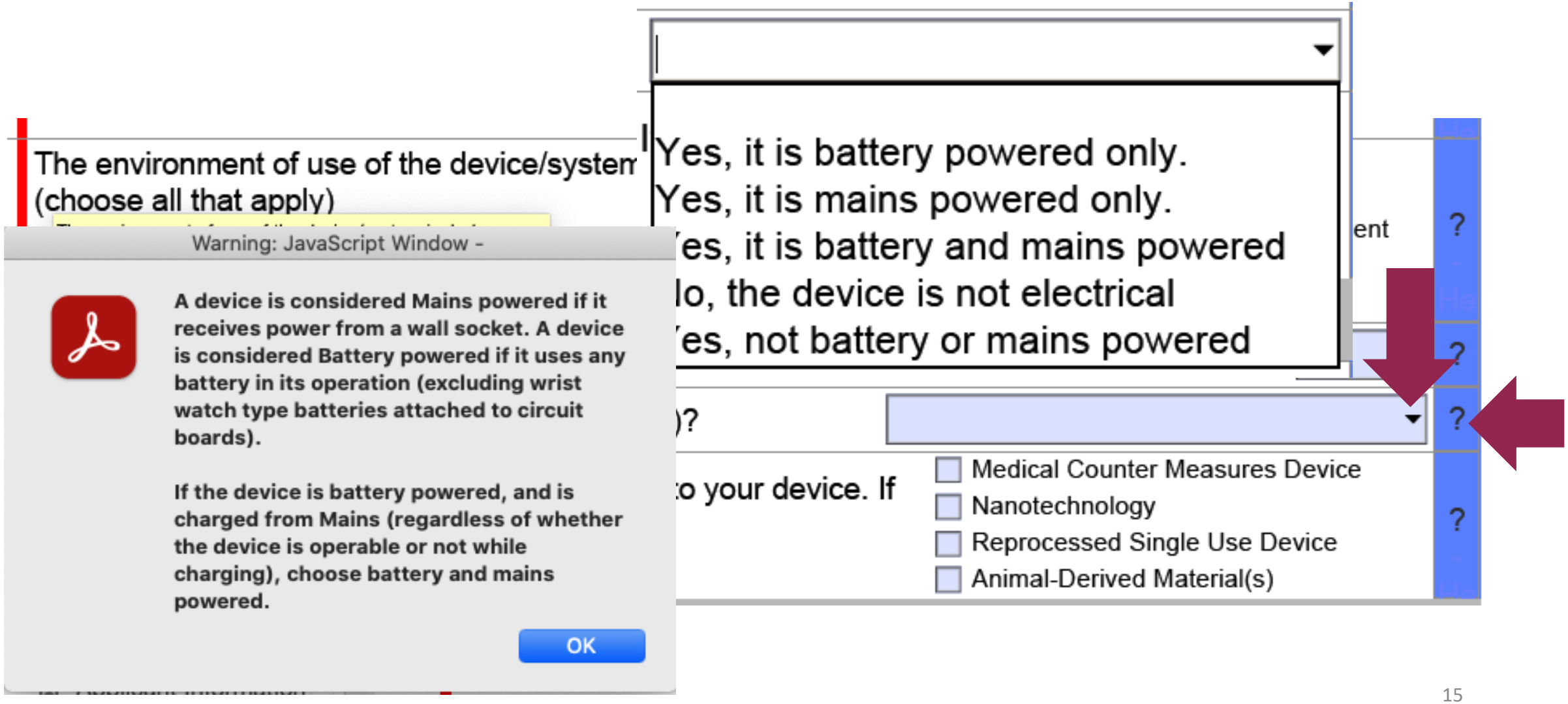
# Strategies for Completion – Pull Down Menu Selections

- Complete from beginning of template
- Utilize help text for clarity as needed
- Ensure each option is evaluated
- When in doubt, try different options to test impact on available fields
- Prepare Word document of proposed information for team collaboration – enter in eSTAR when complete



# Strategies for Completion – Pull Down Menu Selections



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## Strategies for Completion – Text Boxes

- Utilize instructional text
- Where applicable, utilize help text
- Ensure content addresses all requested information
- Do not include confidential information in noted text boxes
  - Many text boxes are used for populating automatic 510(k) Summary feature, if used (noted in instructional text associated with text boxes)
- Prepare Word document of proposed information for team collaboration – enter in eSTAR when complete

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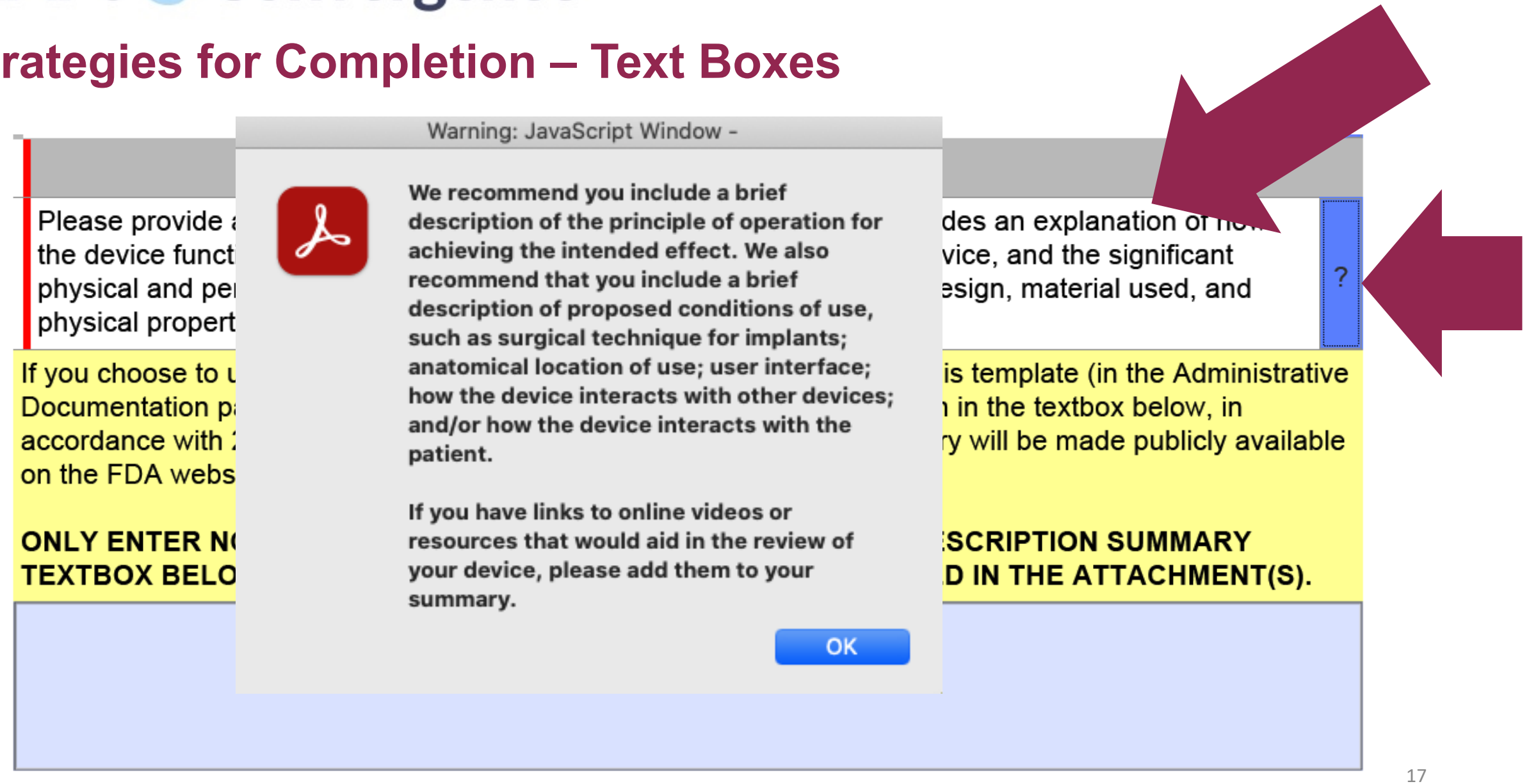
# Strategies for Completion – Text Boxes



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# Addressing Text Box Limitations

- No formatting is currently supported by text boxes
- Some text boxes are used to populate automatic 510(k) Summary (if used)
  - Exclude confidential information from text boxes when indicated in yellow instructional text
- Text boxes have limited space for viewing, so require use of scroll bars if lots of information
- Text Box Recommendations
  - Limit the amount of information provided
  - Include reference to attachment where detailed information is provided
  - Create separate MS Word document for submission preparation to finalize text before pasting in text boxes

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# Strategies for Completion - Attachments

- Utilize instructional text
- Utilize help text
- Ensure content addresses all requested information
- Prepare Word document of proposed information for team collaboration – enter in eSTAR when complete
- Where possible, combine information into a single file
  - Mini submission format
  - Utilize Exhibits to combine
- Use navigation features to facilitate review
  - Pagination
  - Table of contents
  - Bookmarking
  - Hyperlinks
- Use smart naming conventions to facilitate finding the attachments
  - Sequential numbering by order of appearance
  - Title that matches Attachment description in eSTAR
- Acceptable attachment formats include PDF, Word, Excel, and many other formats

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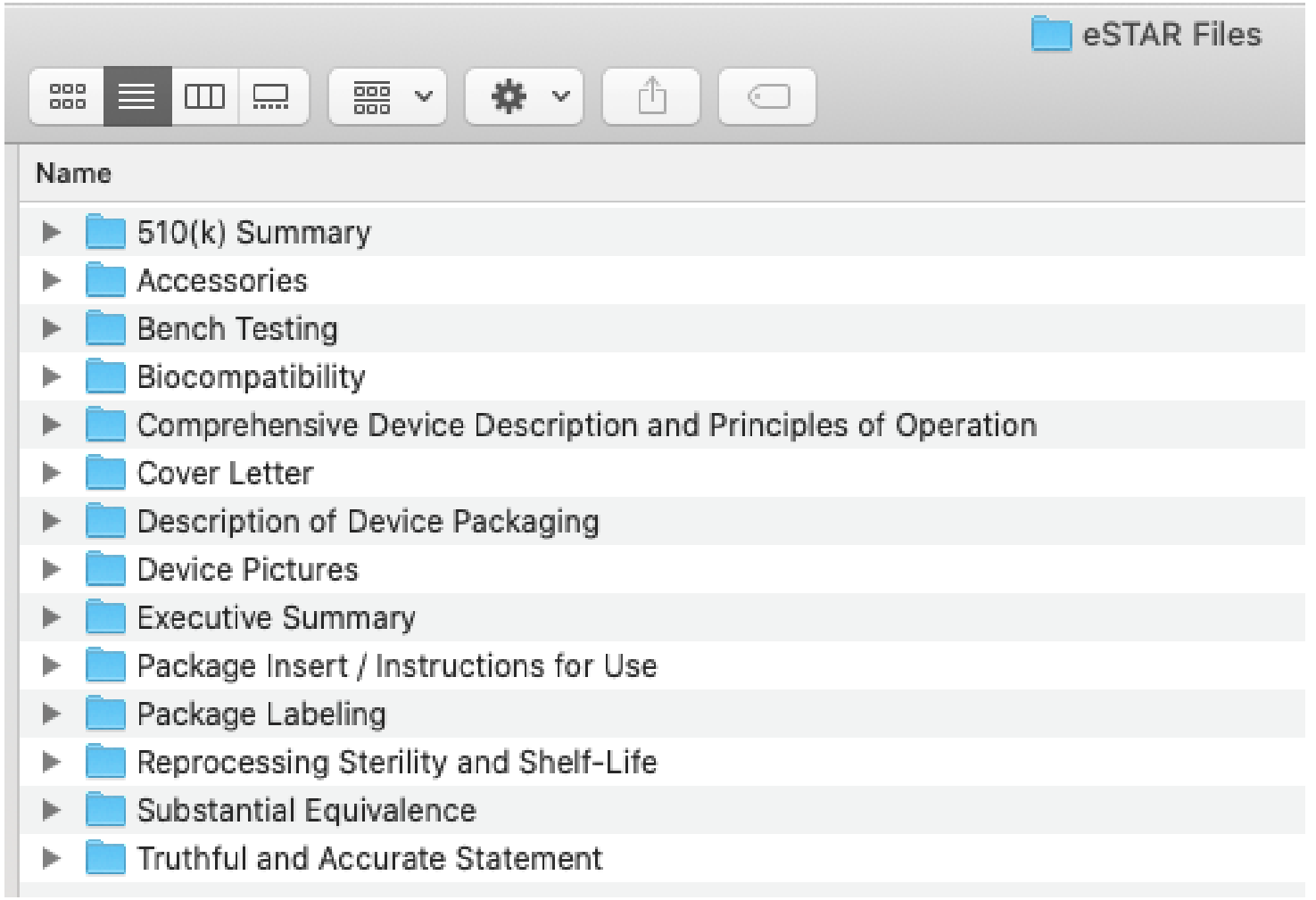
# Strategies for Completion - Attachments

- File Management for Preparation and Internal Company Documentation
  - Create separate folder for each Attachment
  - Organizes content and exhibits for each



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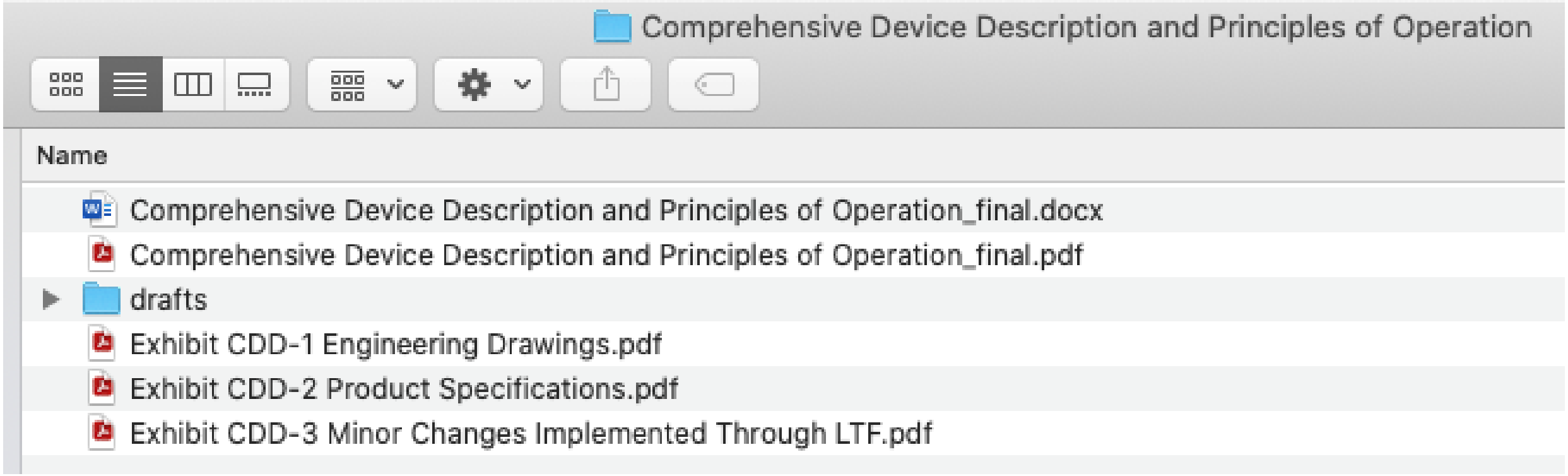
# Strategies for Completion - Attachments



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# Managing eSTAR Attachments

- Naming Conventions
  - Keep concise
  - Consistent format
  - Avoid special characters
  - Include versioning
    - Date or revision
  - Name based on attachment reference in eSTAR
  - Numbering if desired
    - Number to facilitate finding attachments in order of appearance
    - No numbering to facilitate finding attachments by title
  - Compress image and video files
    - Total eSTAR file < 4 GB with CDRH Portal

- 001_Cover Letter 07OCT2023
- 002_Letters of Reference 07OCT2023
- 003_Comprehensive Device Description and Principles of Operation 07OCT2023

**OR**

- Cover Letter 07OCT2023
- Letters of Reference 07OCT2023
- Comprehensive Device Description and Principles of Operation 07OCT2023

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# Act III: Getting to Like You

## Strategies for Completion

## Best Practices for Optimizing eSTAR Submission Presentation

Lisa Pritchard, BSEEE
DuVal & Associates, P.A.

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## Advocacy in Your eSTAR Submission

- eSTAR **is** designed to help ensure the required **evidence** is provided
- eSTAR **is not** designed to help ensure the essential **advocacy** is provided

# What is Advocacy?

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## What is Advocacy?

- Help reviewer understand
  - Why your device is important
  - Why you conducted the testing that you did
  - Why the data provided are appropriate and sufficient

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# How to Achieve Advocacy in an eSTAR Submission?

- **Executive Summary**
  - Consider this essential, not optional, as portrayed in eSTAR template
  - This may be the only part of the submission reviewed by senior management with responsibility for decision
  - Helpful starting point for review team
- **Cover Letter**
  - Use to highlight the use of the Executive Summary
  - Helps ensure review team can benefit from its use
- **Throughout the Submission**
  - Provide information to allow clear understanding of device
  - Include rationale for information provided

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# Executive Summary Contents

- Concise description of the device
- Description of why the product is being introduced
- If 510(k): identification of predicate device and substantial equivalence information
- Summary of data provided
- Description of how the statutory criteria have been met by the data provided
- Conclusion statement that the evidence provided should be considered valid scientific evidence that is sufficient to support the regulatory decision (e.g., 510(k) substantial equivalence determination or De Novo grant decision)

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# Strategies for Resolving Issues During Preparation

- eSTAR templates are continually being updated with policy changes
- If issues are encountered, follow a 3-step process:


eSTAR FAQ @Page 1

FDA eSTAR Website / Guidance


eSTAR Staff

esubpilot@fda.hhs.gov

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# Completing and Submitting Your eSTAR Submission

FDA

## electronic Submission Template And Resource (eSTAR)

*For non-In Vitro Diagnostic Medical Devices* *Version 2.2 (2023-01-10)*

**STATUS: eSTAR INCOMPLETE**

***This eSTAR is incomplete, and will be treated as an improperly prepared eCopy ... not reviewed. You will be notified by a standard eCopy Hold email.***

## Introduction

This template is intended for use in both constructing a non-*in vitro* diagnostic medical device premarket application/ submission, and in being a resource of non-*in vitro* medical device premarket regulations. It contains regulatory information pulled from both International Medical Device Regulators Forum (IMDRF) documents, as well as regulatory documents (e.g., guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

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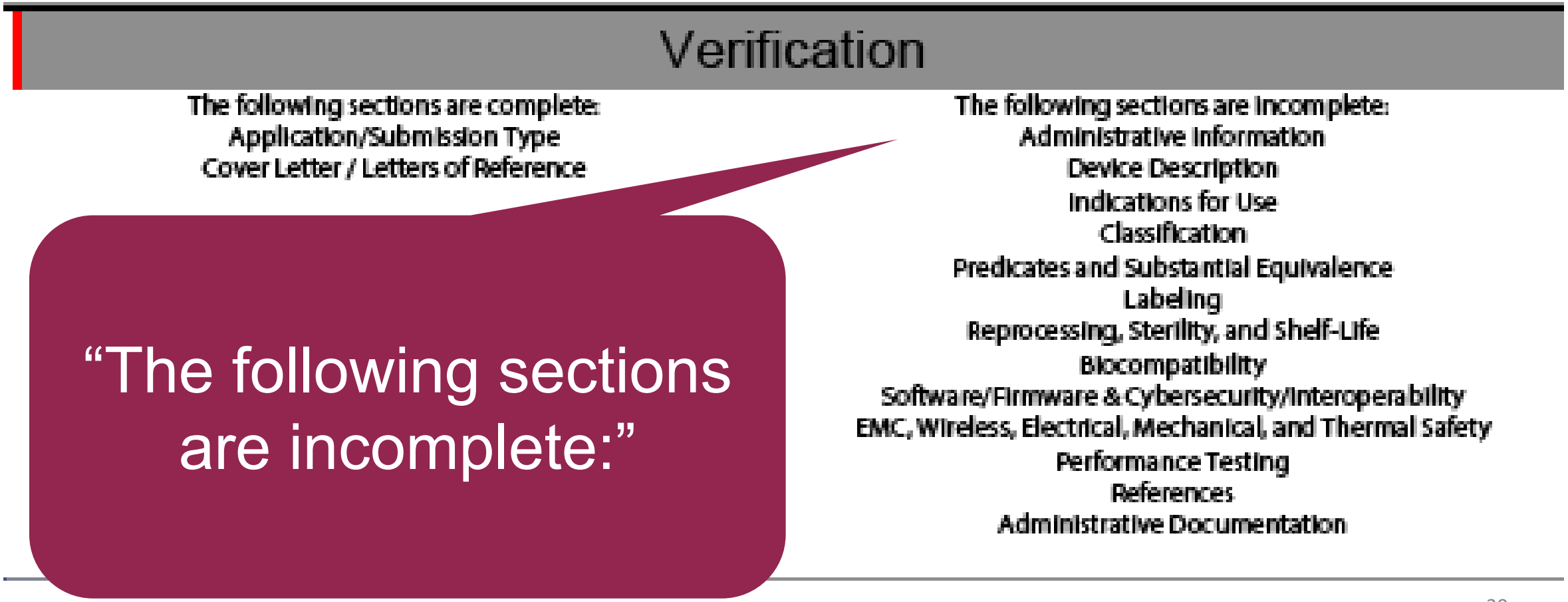
# Completing and Submitting Your eSTAR Submission



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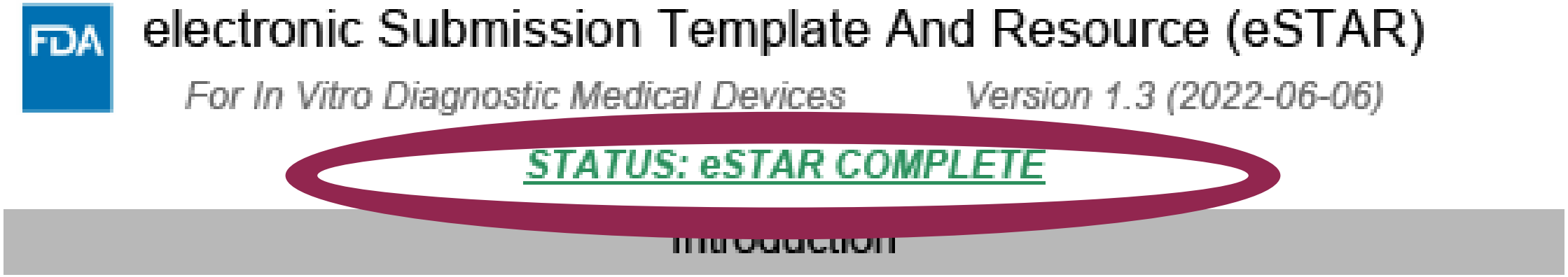
# Completing and Submitting Your eSTAR Submission



FDA

electronic Submission Template And Resource (eSTAR)

*For In Vitro Diagnostic Medical Devices* *Version 1.3 (2022-06-06)*

***STATUS: eSTAR COMPLETE***

Introduction

This template is intended for use in both constructing an *in vitro* medical device premarket application/submission, and in being a resource of *in vitro* medical device premarket regulations. It contains regulatory information pulled from both International Medical Device Regulators Forum (IMDRF) documents, as well as regulatory documents (e.g., guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

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# Completing and Submitting Your eSTAR Submission – Submission Options

- **Document Control Center (De Novo and Pre-Sub eSTARs ONLY)**
  - Signed cover letter
  - Full submission on electronic media
    - CD-ROM
    - Flash Drive
  - Deliver to Document Control Center (Recommend with tracking)
    - US Food and Drug Administration
    - Center for Devices and Radiological Health
    - Document Control Center – WO66-G609
    - 10903 New Hampshire Avenue
    - Silver Spring, MD 20993-0002
- **CDRH Portal (All eSTARS; REQUIRED for 510(k) eSTARS)**
  - Signed cover letter attachment within eSTAR template
  - eSTAR template
    - Most common: all files within the eSTAR template
    - Rare: if extra files cannot be included in eSTAR template, provide as separate volume-based zip file
      - eSTAR template named as volume 1
      - Separate eCopy zip file named as volume 2
  - Upload to CDRH Portal and press send

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# Best Practices – Industry Perspective

- Start population of template from the beginning
- Review help text to ensure attachments address all expected information
- Use smart naming conventions for attachments
- Consider the Executive Summary to be an essential tool for establishing advocacy
- Include reference in the Cover Letter to use of the Executive Summary
- Prepare content outside of eSTAR template to facilitate team review and edit
- Verify green “eSTAR Complete” is present at top of page 1 before the eSTAR is submitted
- If problems, look at FAQ, FDA website, and eSTAR guidance before reaching out to eSTAR staff
- Practice before you are in a time-crunched submission

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# Act IV: Getting to Hope You Like Me

## FDA Review Process
## Responding to Deficiencies
## eSTAR Program Plans

Patrick Axtell, Ph.D.
US Food and Drug Administration

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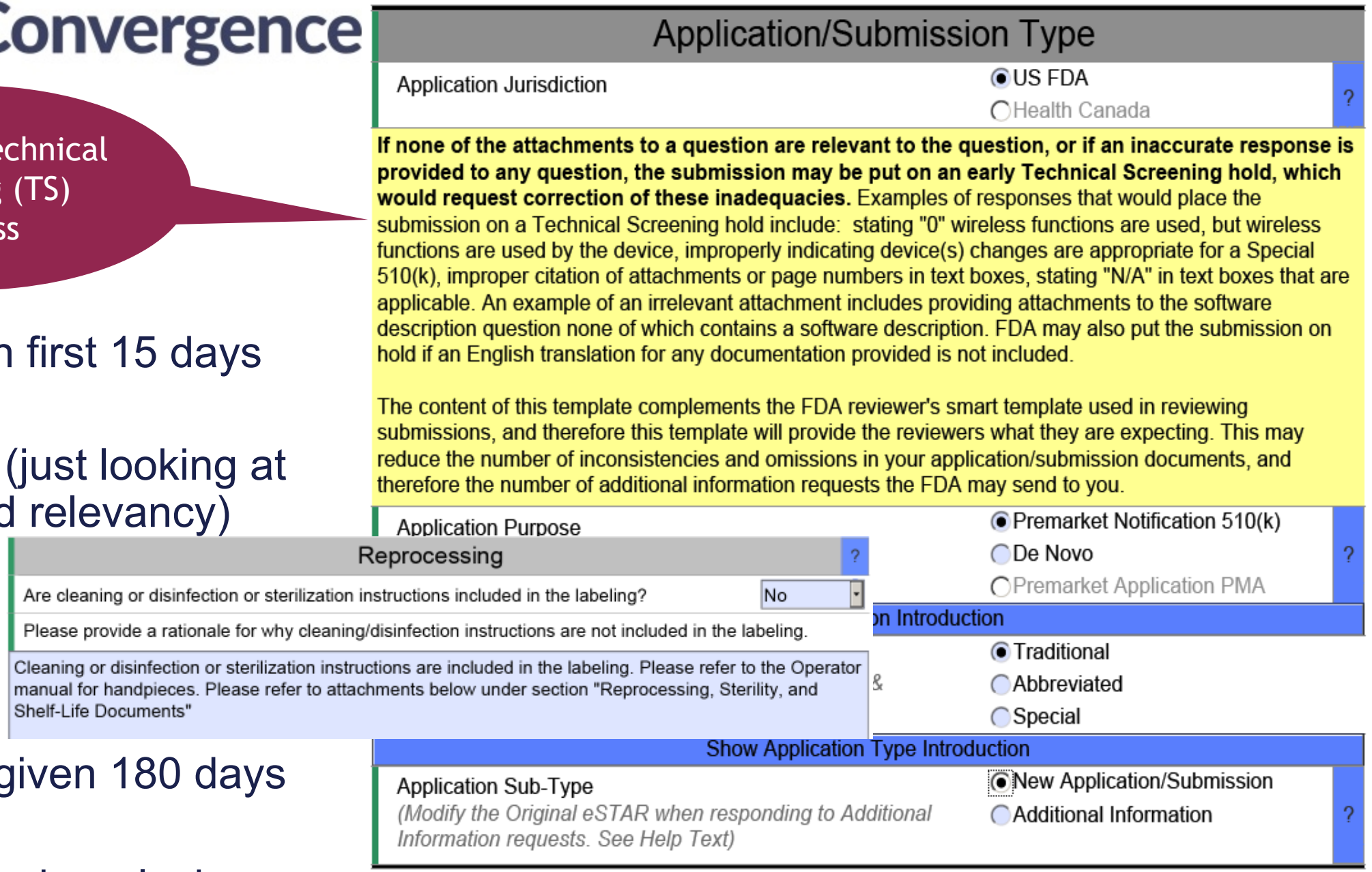
Describes Technical Screening (TS) Process

- Conducted in first 15 days of review
- No checklist (just looking at accuracy and relevancy)
- Applicant is given 180 days to respond
- Resets the review clock



Application/Submission Type

Application Jurisdiction: (•) US FDA ( ) Health Canada

**If none of the attachments to a question are relevant to the question, or if an inaccurate response is provided to any question, the submission may be put on an early Technical Screening hold, which would request correction of these inadequacies.** Examples of responses that would place the submission on a Technical Screening hold include: stating "0" wireless functions are used, but wireless functions are used by the device, improperly indicating device(s) changes are appropriate for a Special 510(k), improper citation of attachments or page numbers in text boxes, stating "N/A" in text boxes that are applicable. An example of an irrelevant attachment includes providing attachments to the software description question none of which contains a software description. FDA may also put the submission on hold if an English translation for any documentation provided is not included.

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Application Purpose: (•) Premarket Notification 510(k) ( ) De Novo ( ) Premarket Application PMA

Reprocessing

Are cleaning or disinfection or sterilization instructions included in the labeling? No

Please provide a rationale for why cleaning/disinfection instructions are not included in the labeling.

Cleaning or disinfection or sterilization instructions are included in the labeling. Please refer to the Operator manual for handpieces. Please refer to attachments below under section "Reprocessing, Sterility, and Shelf-Life Documents"

n Introduction

(•) Traditional ( ) Abbreviated ( ) Special

Show Application Type Introduction

Application Sub-Type
*(Modify the Original eSTAR when responding to Additional Information requests. See Help Text)*
(•) New Application/Submission ( ) Additional Information

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# Additional Information

## Help Text for Application Sub-Type Question:

"New Application/Submission" should be chosen if the application/submission is new.

When visible, the "Change to Application/Submission" option should be chosen if the submission is requesting a change to the content of an approved/authorized application, and the change requires a regulatory review according to the receiving jurisdiction.

"Additional Information" should be chosen when submitting additional information for an application/submission currently under review.

Once you receive an email that your eSTAR passed user fee validation, your original submission is grandfathered in to that eSTAR version. You should always use the eSTAR with your latest information when responding to an Additional Information request. For example, if you already modified your original eSTAR when responding to an Additional Information request and later you receive a second Additional Information request, you should modify the eSTAR you submitted in response to the first Additional Information request.

## When you indicate “Additional Information”:

When submitting a response to an Additional Information or Technical Screening request, you can provide such responses in the section "Additional Information Response" near the end of eSTAR. This means you can update the original eSTAR sent to FDA without transferring content to a newer eSTAR.

For non-510(k) submissions, you may alternatively provide responses and attachments as an eCopy (i.e., an updated eSTAR would not be included in your response).

If the reviewer used interactive review via phone or email, please reply to the reviewer via email with the requested attachments and additional information.

If you are providing additional information that is not in response to an Additional Information request, please indicate this in the Additional Information section near the end of eSTAR.

## Text in “Additional Information” section:

Changes that are necessary to resolve deficiencies should be made in the respective section. If attachments need to be updated, remove the old attachments and replace them with the new attachments.

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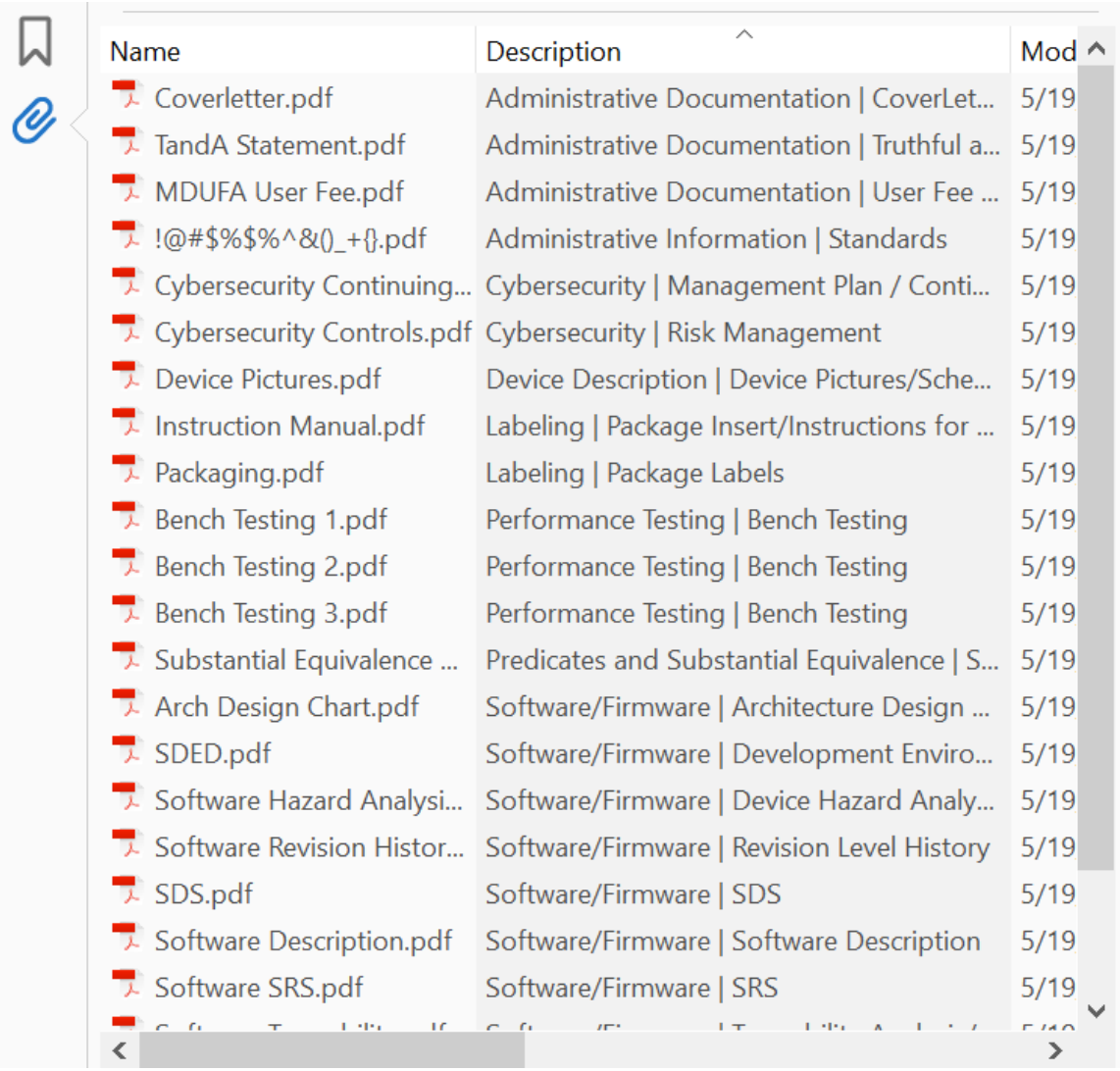
# Attachments

## Attachment Pane in Adobe Acrobat Pro:



| Name | Description | Mod |
|---|---|---|
| Coverletter.pdf | Administrative Documentation \| CoverLet... | 5/19 |
| TandA Statement.pdf | Administrative Documentation \| Truthful a... | 5/19 |
| MDUFA User Fee.pdf | Administrative Documentation \| User Fee ... | 5/19 |
| !@#$%$%^&()_+{}.pdf | Administrative Information \| Standards | 5/19 |
| Cybersecurity Continuing... | Cybersecurity \| Management Plan / Conti... | 5/19 |
| Cybersecurity Controls.pdf | Cybersecurity \| Risk Management | 5/19 |
| Device Pictures.pdf | Device Description \| Device Pictures/Sche... | 5/19 |
| Instruction Manual.pdf | Labeling \| Package Insert/Instructions for ... | 5/19 |
| Packaging.pdf | Labeling \| Package Labels | 5/19 |
| Bench Testing 1.pdf | Performance Testing \| Bench Testing | 5/19 |
| Bench Testing 2.pdf | Performance Testing \| Bench Testing | 5/19 |
| Bench Testing 3.pdf | Performance Testing \| Bench Testing | 5/19 |
| Substantial Equivalence ... | Predicates and Substantial Equivalence \| S... | 5/19 |
| Arch Design Chart.pdf | Software/Firmware \| Architecture Design ... | 5/19 |
| SDED.pdf | Software/Firmware \| Development Enviro... | 5/19 |
| Software Hazard Analysi... | Software/Firmware \| Device Hazard Analy... | 5/19 |
| Software Revision Histor... | Software/Firmware \| Revision Level History | 5/19 |
| SDS.pdf | Software/Firmware \| SDS | 5/19 |
| Software Description.pdf | Software/Firmware \| Software Description | 5/19 |
| Software SRS.pdf | Software/Firmware \| SRS | 5/19 |

## eSTAR accepts nearly every attachment typ

The attachment "Updates to SMART for Publication of EMC Guidance v2.zip" is not an acceptable attachment type.

Please do not attach the following file types in eSTAR, since these file types cannot be opened in or saved from a PDF form:
- compressed/archived file types (e.g., .zip)
- macro-enabled documents (e.g., .docm, .xlsm)
- binary files or executables (e.g., .exe)

Please combine similar documents where possible to reduce the number of attachments. Combining PDFs is possible with Adobe Acrobat Pro by choosing "Tools" then "Combine Files."

If you must submit any of these file types in an eSTAR, please email eSubPilot@fda.hhs.gov for help.

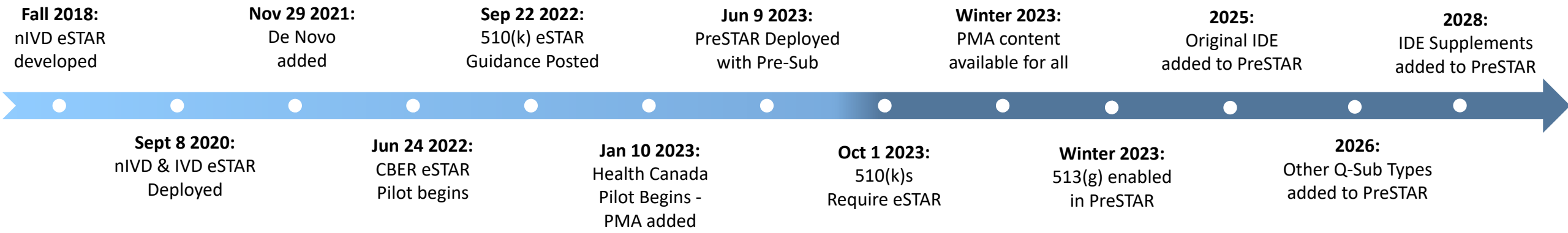
## Don't delete or add with the attachment pane:

The following attachments were added with the "Add Attachment" buttons but then manually deleted from the eSTAR Attachment Pane (i.e., the "Delete Attachment" buttons were not used).

Please click the "Delete Attachment" button next to each of these attachments (use Edit->Find to find each) and then, if you would like to re-add any, click the "Add Attachment" button to re-add each to this eSTAR. If the eSTAR was already signed, the original signee should right-click and clear all their signatures first (e.g., in the T&A Statement, and/or in the Declaration of Conformity) before you click "Delete Attachment" for each missing attachment.

Biocompatibility Test Reports.pdf

# Timeline and Plans




PDF

**nIVD eSTAR**

510(k) [Trad, Abbrev, Spec]

De Novo

PMA [Orig, PTS, 180D, RT]*

HDE (future)

PDF

**IVD eSTAR**

510(k) [Trad, Abbrev, Spec]

De Novo

PMA [Orig, PTS, 180D, RT]*

HDE (future)

PDF

**PreSTAR**

513(g)

IDE*

Q-Sub

* May not include Reports, which may be more efficiently handled via webforms or standalone non-dynamic

# International Pilot with Health Canada

- Testing HC Class III, IV, and FDA PMA submission types, as well as multi-region use
- Nine participants are submitting the same eSTAR to both Health Canada and FDA
- 510(k) and PMA submissions included for FDA (no De Novo made it in the pilot)
- Class III and IV submissions included for Health Canada

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# Summary / Q&A

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# Helpful eSTAR Links

- FDA eSTAR program with links to current eSTAR templates
- FDA Guidance: *Electronic Submission Template for Medical Device 510(k) Submissions*, issued October 2, 2023
- FDA ***Draft*** Guidance: Electronic Submission Template for Medical Device De Novo Requests, issued September 29, 2023
- FDA Guidance: *Format for Traditional and Abbreviated 510(k)s*, issued September 13, 2019
- FDA Guidance: *The Special 510(k) Program*, issued September 13, 2019
- FDA Guidance: *The Abbreviated 510(k) Program*, issued September 13, 2019
- FDA Guidance: *Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions*, issued December 20, 2019
- FDA Guidance: De Novo Classification Process (Evaluation of Automatic Class III Designation), issued October 5, 2021
- FDA Guidance: *Requests for Feedback and Meetings for Medical Device Subissions: The Q-Submission Program*, issued June 2, 2023

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# DuVal & Associates eSTAR Client Alert Series


http://www.duvalfdalaw.com/resourcesClientAlerts.html

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# Questions?


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