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FDA eSTAR: What You Must Know

Michelle Lott, RAC
Principal & Founder, leanRAQA

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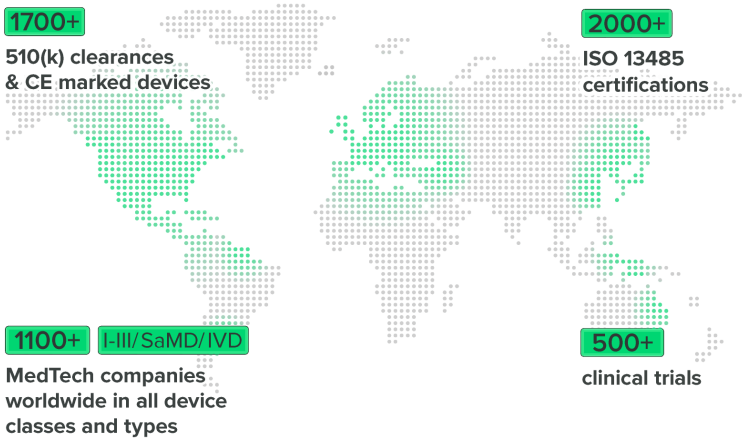

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What is eSTAR?

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eSTAR Basics

- The eSTAR is an interactive PDF form that guides applicants through the process of preparing a comprehensive medical device submission.

- Software and Operating System Required: Adobe Acrobat Pro DC or the latest Adobe Acrobat Pro Windows versions or Foxit

This template contains:

- Automation (Form construction, autofill)
- Content and structure complementary to CDRH internal review templates
- Integration of multiple resources (ie, guidances and databases)
- Guided construction for each section
- Automatic verification!

michelle@leanraqa.com

Advantages for FDA

- Facilitate FDA reviews by receiving information in templates complementary to CDRH internal templates and enable more efficient and consistent reviews.

- Improve overall productivity, enabling the agency's review staff to put more time and resources into evaluation applications for devices that pose the highest potential risks to patients.

- Fulfills MDUFA IV commitment to streamline premarket notification review process, part of FDA's ongoing effort to ensure patients more timely access to safe, effective and high-quality medical devices.

When do I need to pay attention?...Now

- Starting October 1, 2023, all 510(k) submissions (unless exempted) must be submitted as electronic submissions using eSTAR.

Pre-Submissions, De Novo, and PMAs submitted using eSTAR remain voluntary until further notice.

Why do I need to pay attention…Now

- Starting Feb 4, 2024, only version 5 of the template will be available (older versions retired)

Note: This link actually downloads **v5.1**

Current eSTAR Versions[1]:

eSTAR PDF Template[1] (you *MUST* right-click and download)	This eSTAR template may be used to submit to CDRH:
Updated Version: Non-In Vitro Diagnostic eSTAR Version 5	510(k), De Novo, and PMA[4]: medical device submissions for Non-In Vitro Diagnostic devices
This eSTAR version will be retired on February 4, 2024: Non-In Vitro Diagnostic eSTAR Version 4	510(k) and De Novo medical device submissions for Non-In Vitro Diagnostic devices
Updated Version: In Vitro Diagnostic eSTAR Version 5	510(k), De Novo, and PMA medical device submissions for In Vitro Diagnostic devices
This eSTAR version will be retired on February 4, 2024: In Vitro Diagnostics eSTAR Version 4	510(k) and De Novo medical device submissions for In Vitro Diagnostic devices
Early Submission Requests eSTAR (PreSTAR) Beta Version	Pre-Submissions (a type of Q-Submission) for Non-In Vitro and In Vitro Diagnostic devices.[3]

Version 5 Updates

- Version 5 was released on December 6, 2023 and included some significant changes:
  - Increased **cybersecurity** details
  - **Biocompatibility** improvements
  - **Clinical Investigation** updates

Changing Strategy to Documentation Review

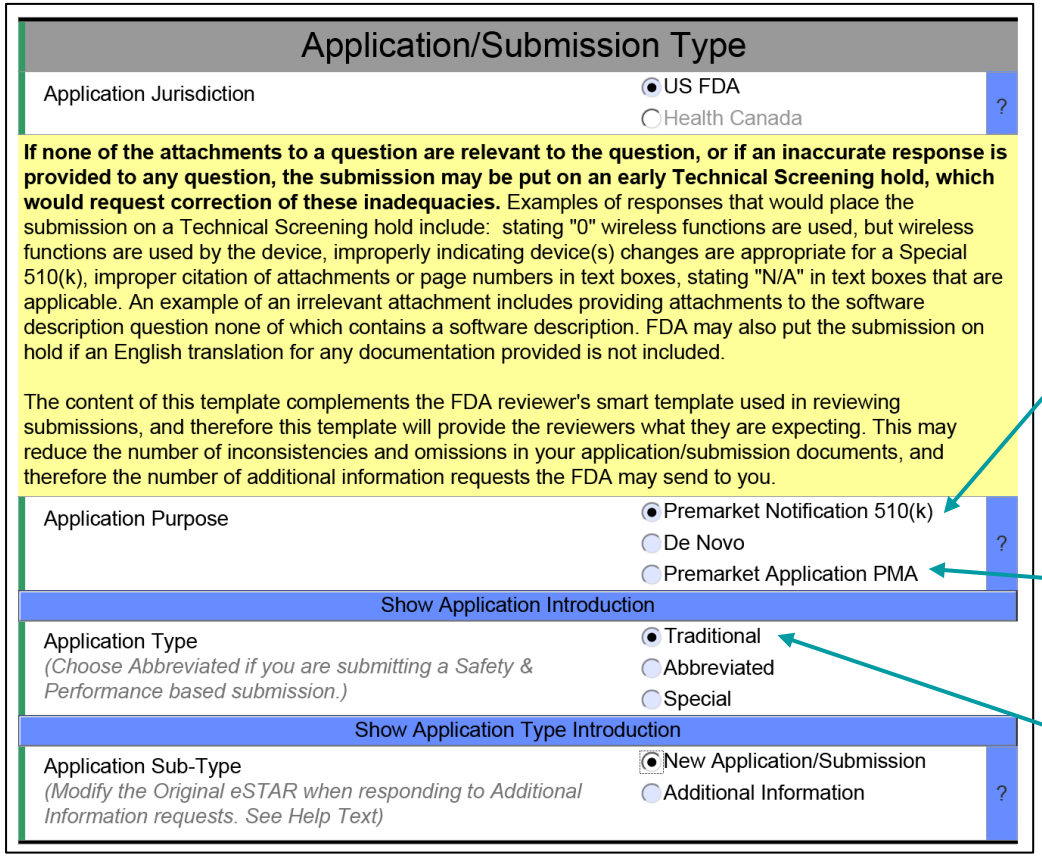
Prior to eSTAR

FDA would pull the documentation out of manufacturers with additional requests through the RTA and review processes.

With eSTAR

Manufacturers are expected to provide all relevant information in the eSTAR template

Interactive Dynamic Format



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.

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)
- ( ) 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

?

Selecting Application Purpose unlocks other applicable sections to be completed

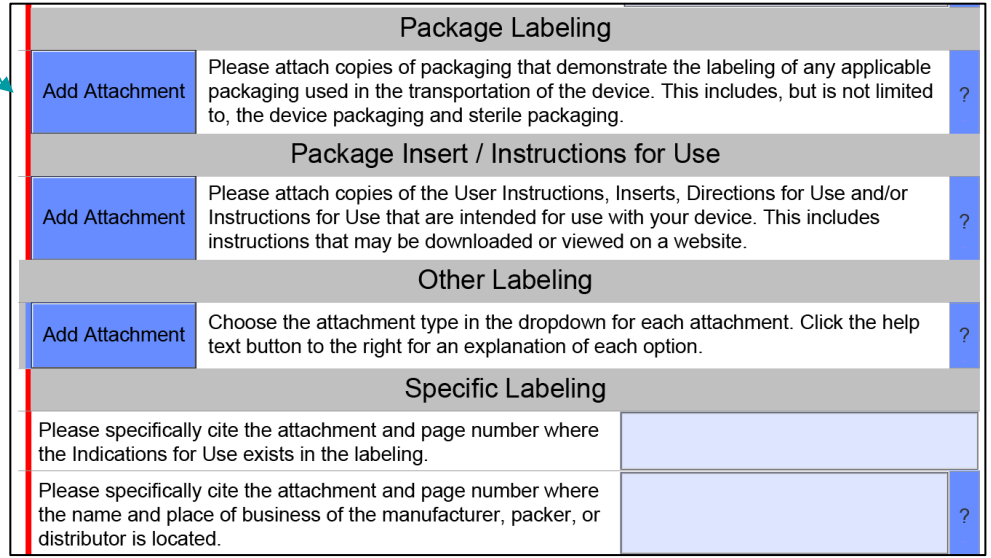
PMA functionality added in version 5 on 6 Dec 2023!

Selecting Application Type further refines the application

Recommendations for Streamlining Attachments

- Consider combining attachments so only one attachment is provided to each question in eSTAR.
- Bookmarks or Table of Contents recommended.
- Use smart naming conventions to facilitate finding attachments
  - Sequential numbering
  - Title that matches attachment description in eSTAR
  - Acceptable attachment formats: PDF, Word, Excel, MP3, MP4 …

…No more MISC FILES folder!



Review all questions…carefully!

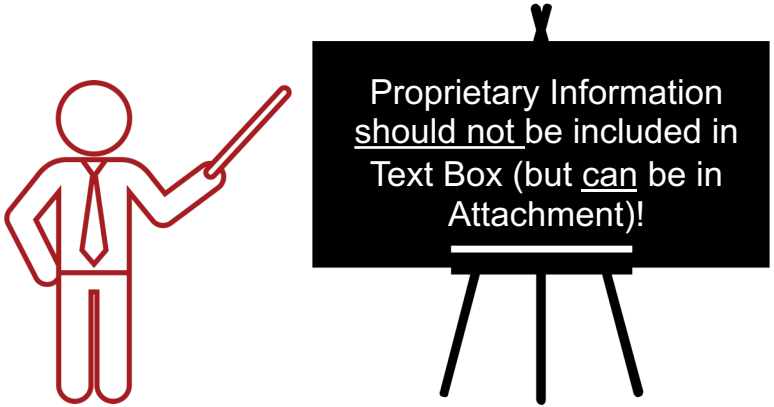
- Device Description included in template and in Attachment

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DEVICE DESCRIPTION SUMMARY TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

Device Description Text Box

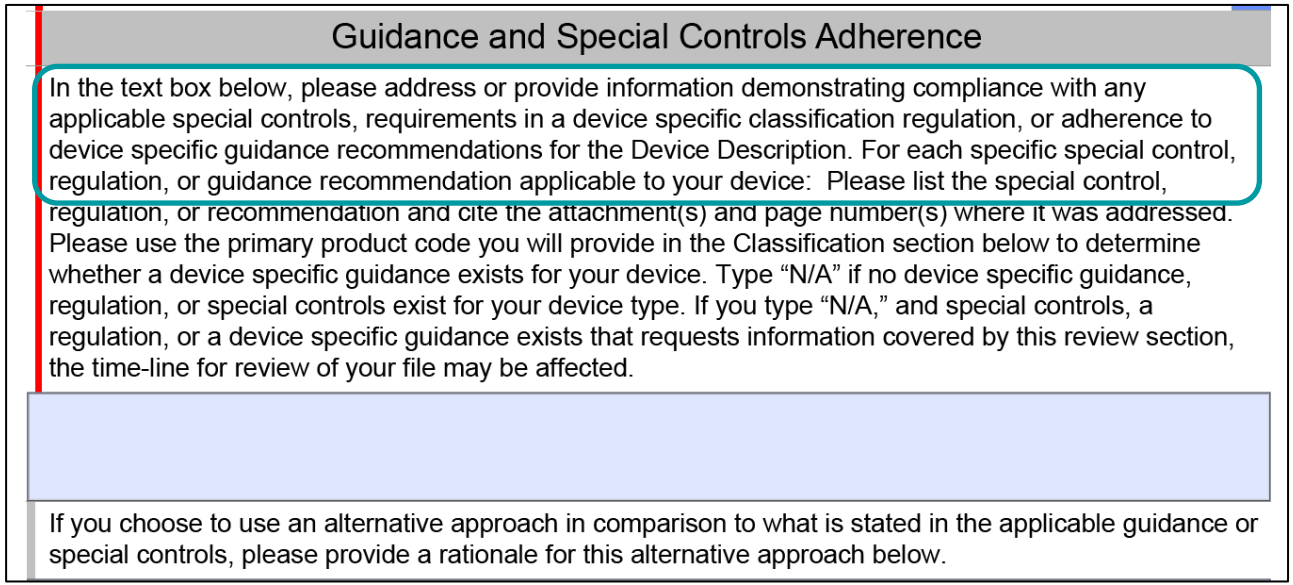
Add Attachment | Comprehensive Device Description and Principles of Operation Documentation | ?

Device Description Attachment



eSTAR vs. normal 510(k)

- Additional traceability information related to guidance(s) used
- Each section has a template to fill in applicable guidance(s)



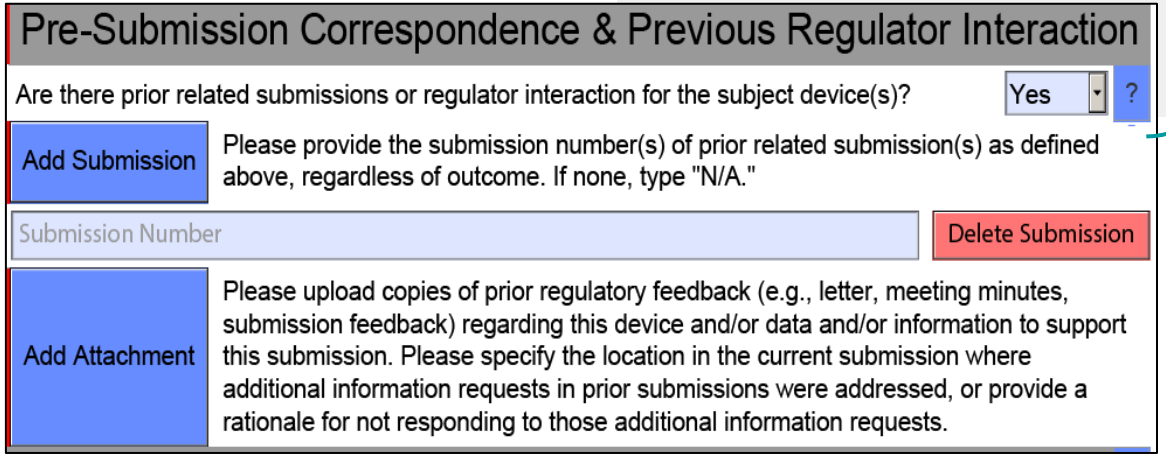
Guidance and Special Controls Adherence

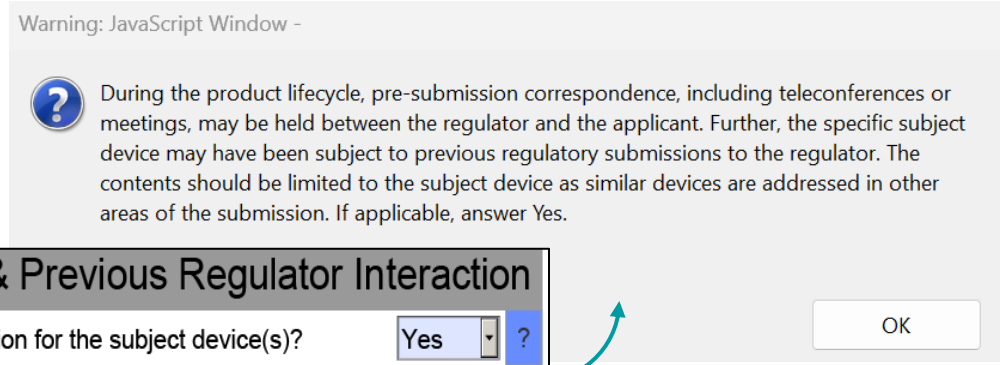
In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Device Description. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you will provide in the Classification section below to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

eSTAR vs. normal 510(k)

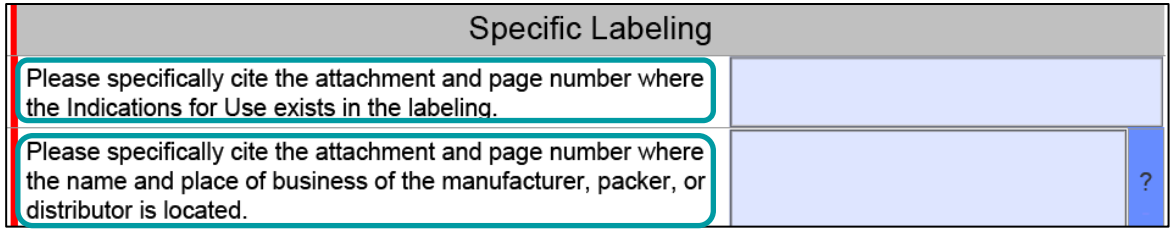
- **Ensure to attach all FDA Correspondence directly into the eSTAR application, such as:**
  - 513(g)s
  - Pre-submissions
  - NSE or Withdrawals
  - EUAs



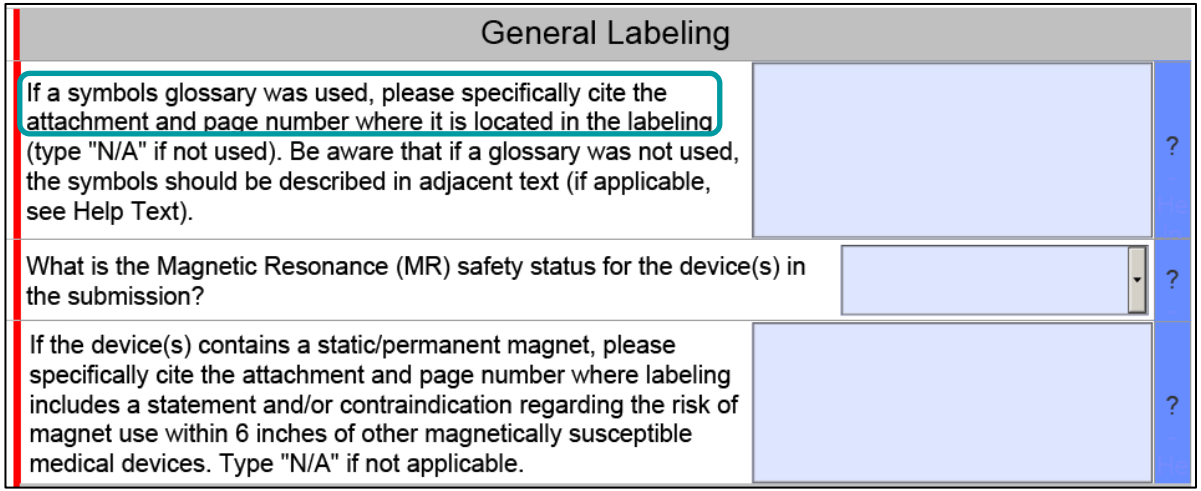


eSTAR vs. normal 510(k)

- **Requirement in eSTAR template:**
  - Attachment and page #s where critical info is located



Specific Labeling	
Please specifically cite the attachment and page number where the Indications for Use exists in the labeling.	
Please specifically cite the attachment and page number where the name and place of business of the manufacturer, packer, or distributor is located.	?



General Labeling		
If a symbols glossary was used, please specifically cite the attachment and page number where it is located in the labeling (type "N/A" if not used). Be aware that if a glossary was not used, the symbols should be described in adjacent text (if applicable, see Help Text).		?
What is the Magnetic Resonance (MR) safety status for the device(s) in the submission?		?
If the device(s) contains a static/permanent magnet, please specifically cite the attachment and page number where labeling includes a statement and/or contraindication regarding the risk of magnet use within 6 inches of other magnetically susceptible medical devices. Type "N/A" if not applicable.		?

Some Sections are Different…

- **eSTAR template incorporates some forms, which no longer need to be filled out separately.**
  - Form 3514 (submission cover sheet)
  - Form 3881 (indications for use)
- **eSTAR template has also excluded some previously-required forms:**
  - Included in *FDA Guidance: Format for Traditional and Abbreviated 510(k)s* (September 2019) as **Required Sections**

FDA Guidance (September 2019) - **Required Sections**	**In eSTAR template**
Class III Summary Statement	Not Included
Financial Disclosure	Not Included*
Declaration Summary Reports	Separate Reports no longer required to upload. These are now generated for you!

*Note: Financial disclosure *statements* are still required when using clinical data to support submission

SWOT Analysis

S.W.O.T. Analysis

Strengths

- No Refuse to Accept (RTA) review due to the use of automatic verification

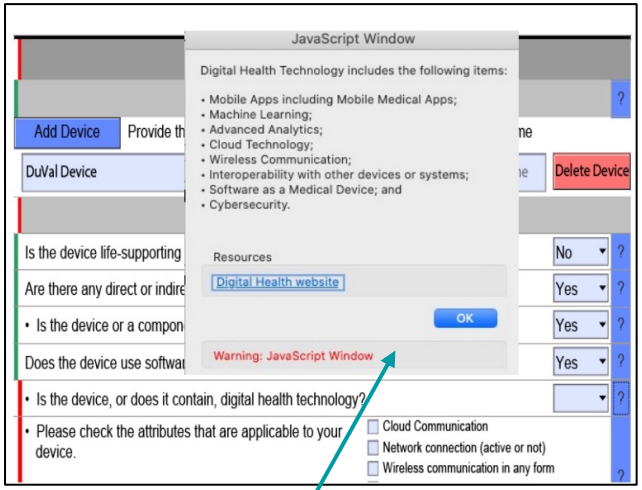
In theory, this could mean faster substantive interaction…but some have said they've **seen no difference**

One eSTAR review took **TWO WEEKS**, no faster than RTA review

Strengths

- Aligns with FDA internal review templates
- Integration of guidance expectations

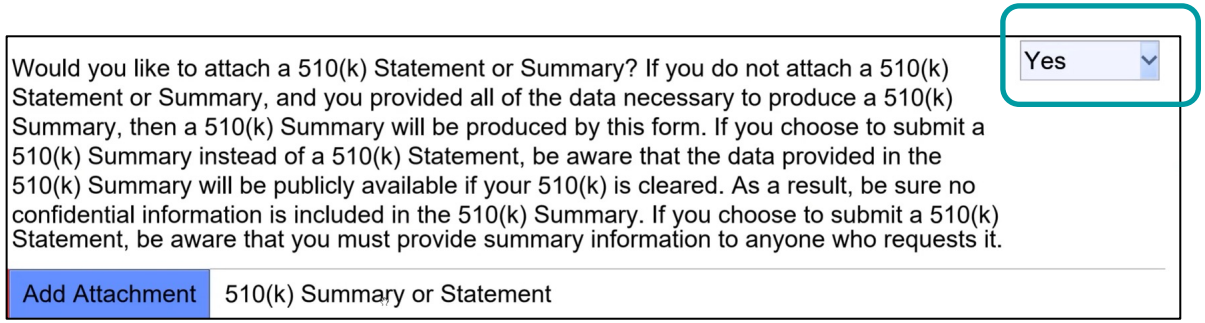
Error message pops up if responses do not make sense



Blue question marks link to helpful pop ups

Strengths, continued

- Option to automate the 510(k) Summary creation



Automatic 510(k) Summary Generation

Substantial Equivalence Comparison	
If the device has different indications for use in comparison to the predicate device(s), describe why the differences do not constitute a new intended use. If the indications for use are the same, state this in the text box below. If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), and the Indications are different in comparison to your predicate device(s), you must include the information from 21 CFR 807.92(a)(5) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared. **ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE RATIONALE TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).**	?
Indications for use are identical in comparison to the predicate device.	

Any topic highlighted in yellow = part of 510(k) Summary

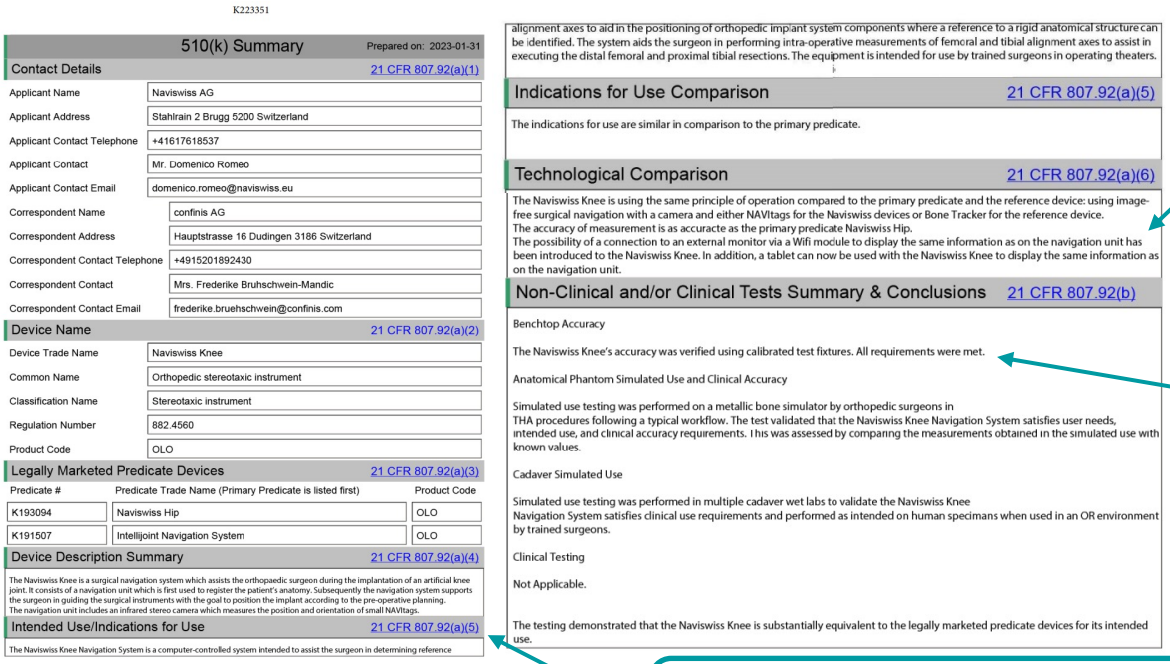
Info included here will be automatically populated into final 510(k) Summary **if 'No' is selected**.

Would you like to attach a 510(k) Statement or Summary? If you do not attach a 510(k) Statement or Summary, and you provided all of the data necessary to produce a 510(k) Summary, then a 510(k) Summary will be produced by this form. If you choose to submit a 510(k) Summary instead of a 510(k) Statement, be aware that the data provided in the 510(k) Summary will be publicly available if your 510(k) is cleared. As a result, be sure no confidential information is included in the 510(k) Summary. If you choose to submit a 510(k) Statement, be aware that you must provide summary information to anyone who requests it.	No

- **Tip: Do not include any proprietary information in text boxes for yellow prompts!**

Automatic 510(k) Summary: Example

- Naviswiss Knee (K223351)



K223351

510(k) Summary Prepared on: 2023-01-31

Contact Details 21 CFR 807.92(a)(1)

Applicant Name	Naviswiss AG
Applicant Address	Stahlrain 2 Brugg 5200 Switzerland
Applicant Contact Telephone	+41617618537
Applicant Contact	Mr. Domenico Romeo
Applicant Contact Email	domenico.romeo@naviswiss.eu
Correspondent Name	confinis AG
Correspondent Address	Hauptstrasse 16 Dudingen 3186 Switzerland
Correspondent Contact Telephone	+4915201892430
Correspondent Contact	Mrs. Frederike Bruhschwein-Mandic
Correspondent Contact Email	frederike.bruehschwein@confinis.com

Device Name 21 CFR 807.92(a)(2)

Device Trade Name	Naviswiss Knee
Common Name	Orthopedic stereotaxic instrument
Classification Name	Stereotaxic instrument
Regulation Number	882.4560
Product Code	OLO

Legally Marketed Predicate Devices 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K193094	Naviswiss Hip	OLO
K191507	Intellijoint Navigation System	OLO

Device Description Summary 21 CFR 807.92(a)(4)

The Naviswiss Knee is a surgical navigation system which assists the orthopaedic surgeon during the implantation of an artificial knee joint. It consists of a navigation unit which is first used to register the patient's anatomy. Subsequently the navigation system supports the surgeon in guiding the surgical instruments with the goal to position the implant according to the pre-operative planning. The navigation unit includes an infrared stereo camera which measures the position and orientation of small NAVItags.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Naviswiss Knee Navigation System is a computer-controlled system intended to assist the surgeon in determining reference alignment axes to aid in the positioning of orthopedic implant system components where a reference to a rigid anatomical structure can be identified. The system aids the surgeon in performing intra-operative measurements of femoral and tibial alignment axes to assist in executing the distal femoral and proximal tibial resections. The equipment is intended for use by trained surgeons in operating theaters.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are similar in comparison to the primary predicate.

Technological Comparison 21 CFR 807.92(a)(6)

The Naviswiss Knee is using the same principle of operation compared to the primary predicate and the reference device: using image-free surgical navigation with a camera and either NAVItags for the Naviswiss devices or Bone Tracker for the reference device.
The accuracy of measurement is as accuracte as the primary predicate Naviswiss Hip.
The possibility of a connection to an external monitor via a Wifi module to display the same information as on the navigation unit has been introduced to the Naviswiss Knee. In addition, a tablet can now be used with the Naviswiss Knee to display the same information as on the navigation unit.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Benchtop Accuracy

The Naviswiss Knee's accuracy was verified using calibrated test fixtures. All requirements were met.

Anatomical Phantom Simulated Use and Clinical Accuracy

Simulated use testing was performed on a metallic bone simulator by orthopedic surgeons in THA procedures following a typical workflow. The test validated that the Naviswiss Knee Navigation System satisfies user needs, intended use, and clinical accuracy requirements. This was assessed by comparing the measurements obtained in the simulated use with known values.

Cadaver Simulated Use

Simulated use testing was performed in multiple cadaver wet labs to validate the Naviswiss Knee Navigation System satisfies clinical use requirements and performed as intended on human specimans when used in an OR environment by trained surgeons.

Clinical Testing

Not Applicable.

The testing demonstrated that the Naviswiss Knee is substantially equivalent to the legally marketed predicate devices for its intended use.

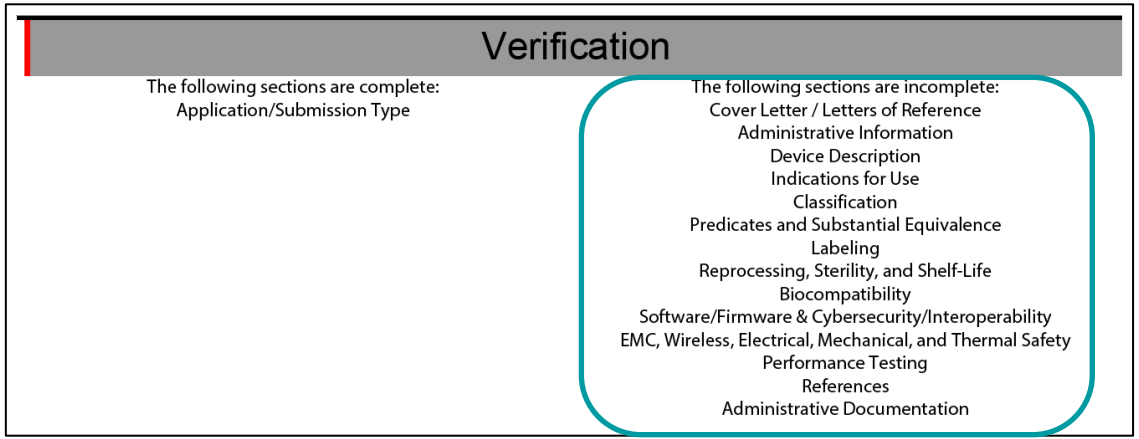
May include some info the manufacturer **may not typically provide to the public**

Format is more standardized **but can be clunky**

Easy to tell this is generated straight from eSTAR – **same format as template**

Strengths, continued

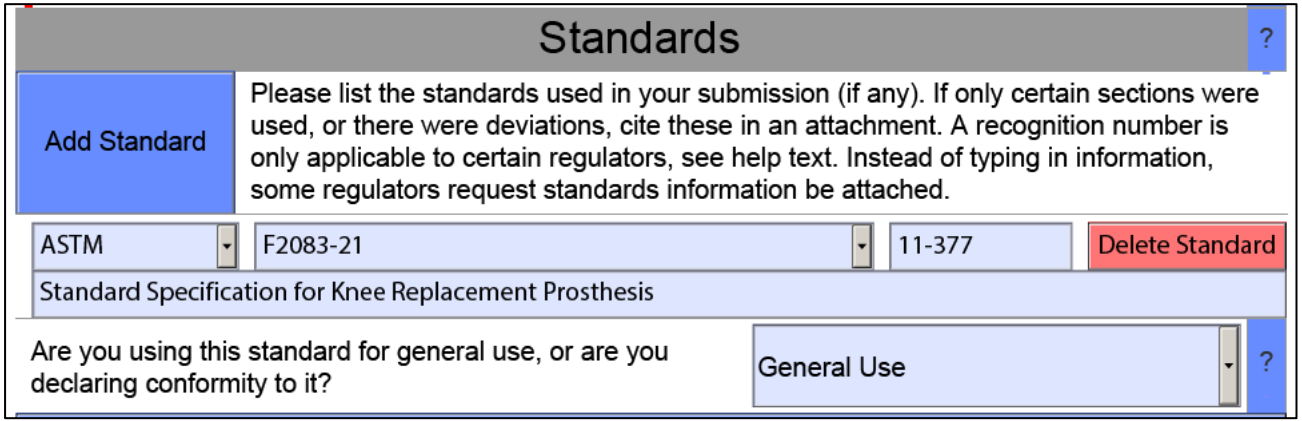
- Automated completeness verification



- Tip: Always make sure all sections are flagged green (not red) to confirm completeness

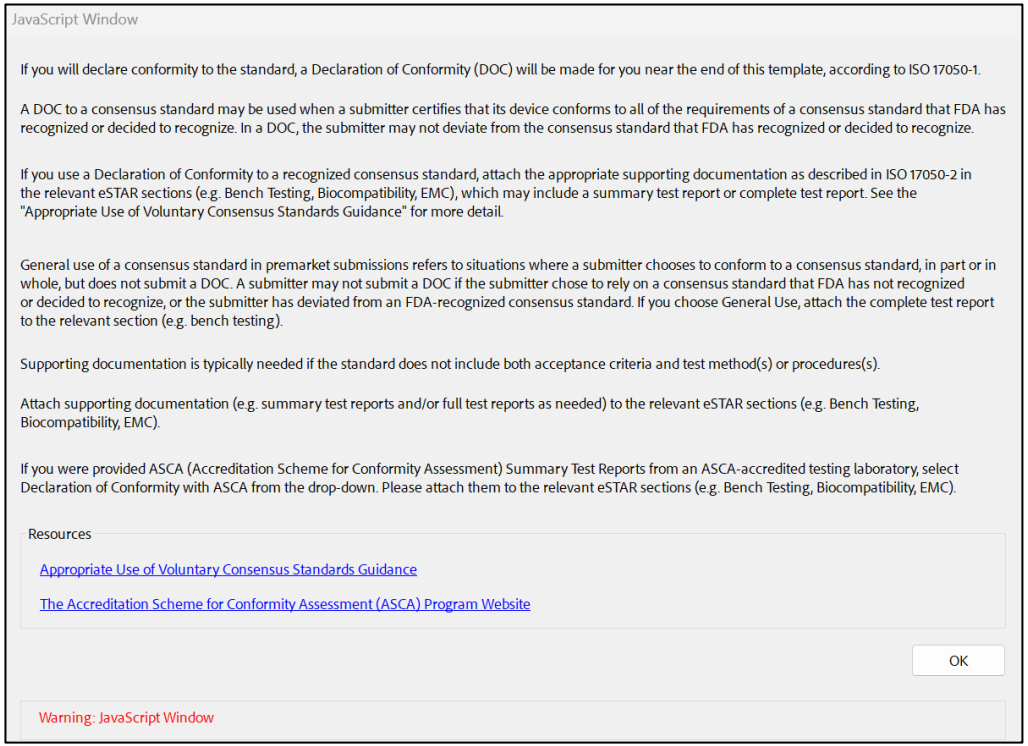
Strengths, continued

- **No more messing with Standards Forms**
  - Auto-populates FDA recognition number AND title



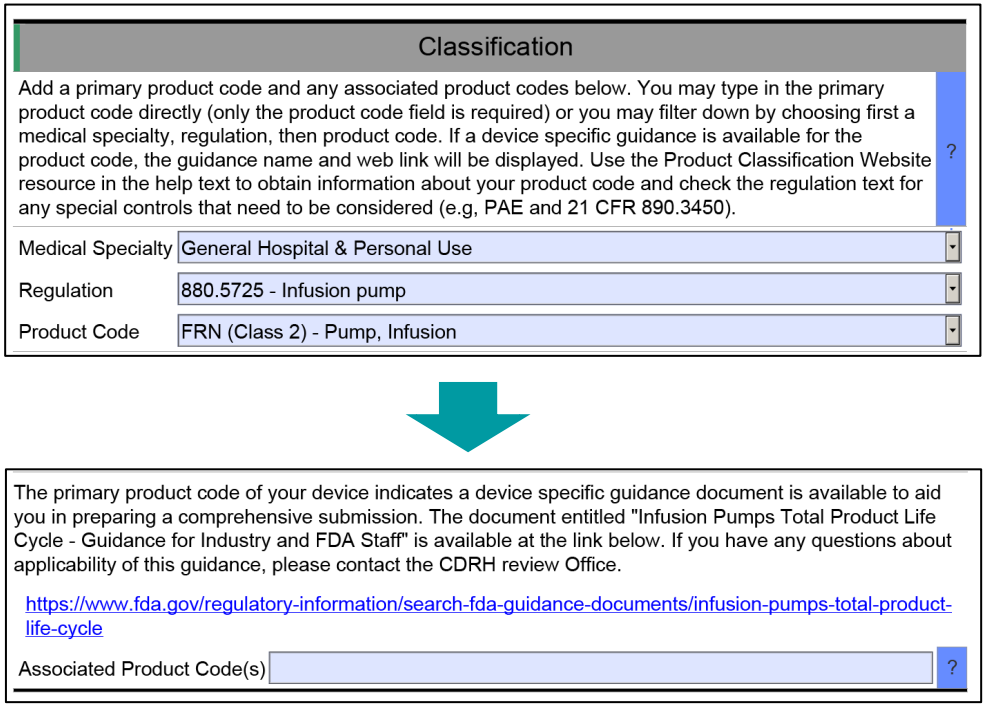
Strengths, continued

- **Standards:** General Use v Declaration of Conformity



Strengths, continued

- Automatically generate applicable guidance documents based on Product Code



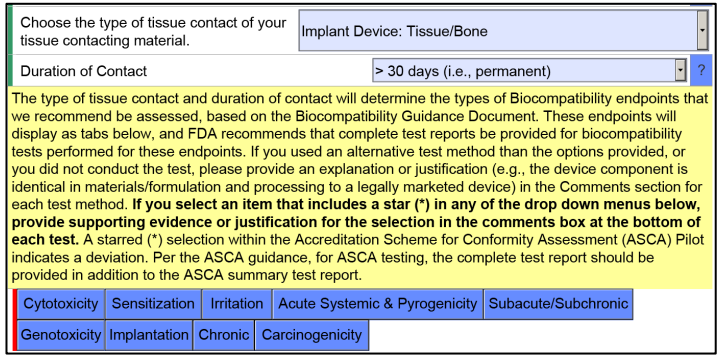
Caution! Don't rely on this feature to fulfill all requirements. eSTAR templates only recommend Final Guidances that are broadly applicable.

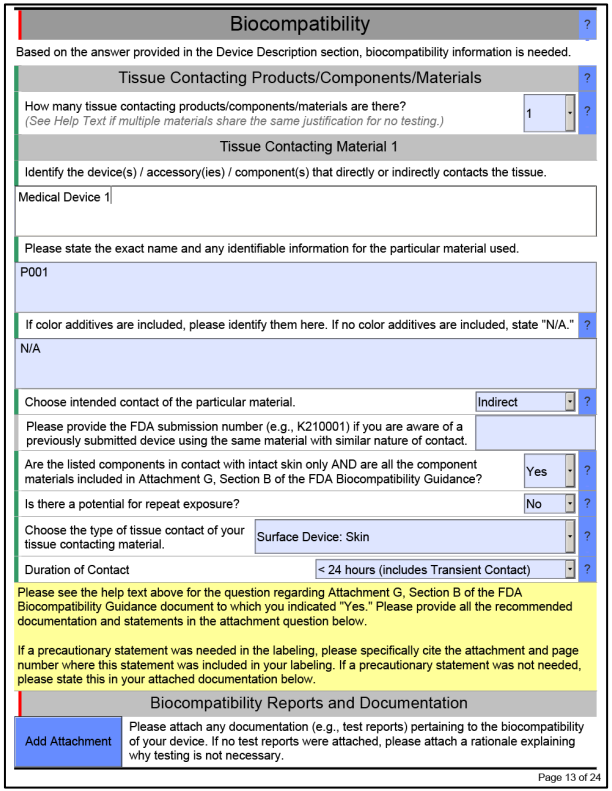
Does not include:

- Draft Guidance documents
- Highly specific guidances for a specific product or technological feature

And the Template Continues to Improve – 5.0 and beyond

- **Biocompatibility Template Improvements**
  - Older versions of template required the user to click through individual tabs per test (regardless if unnecessary)

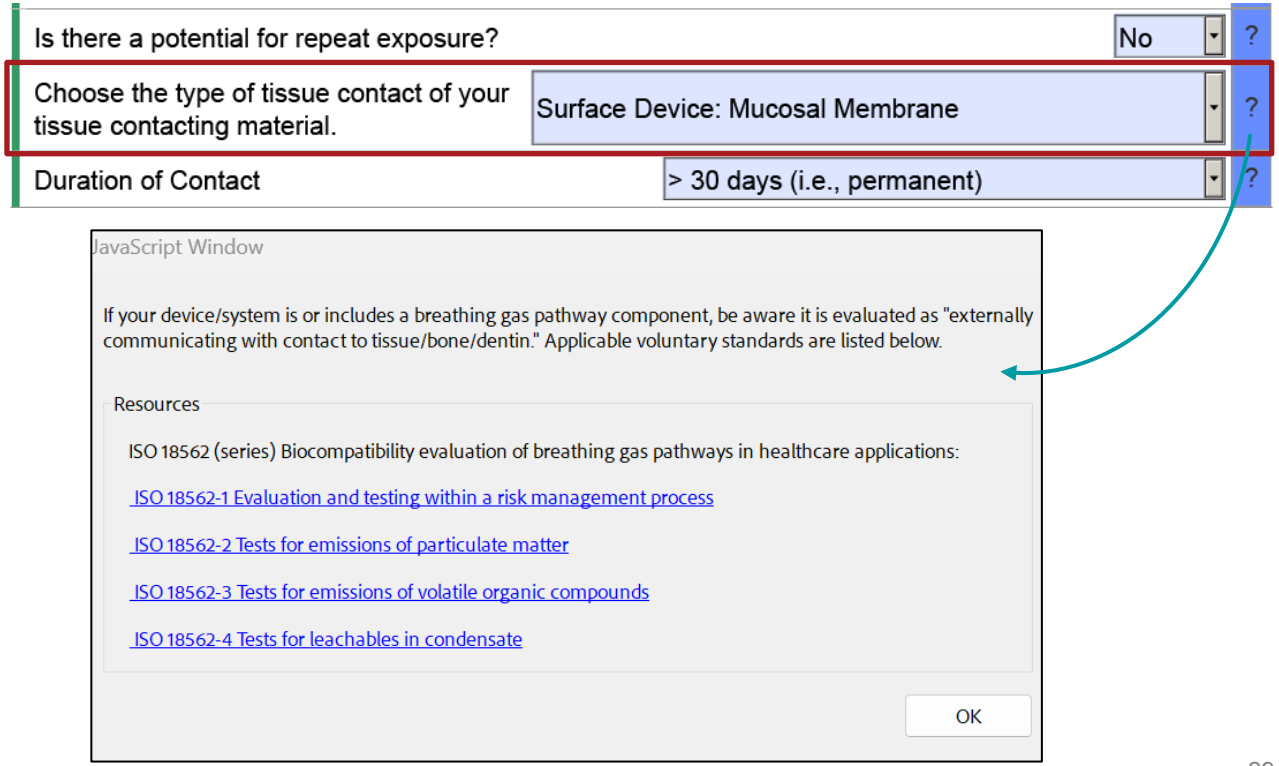




And the Template Continues to Improve – 5.0 and beyond

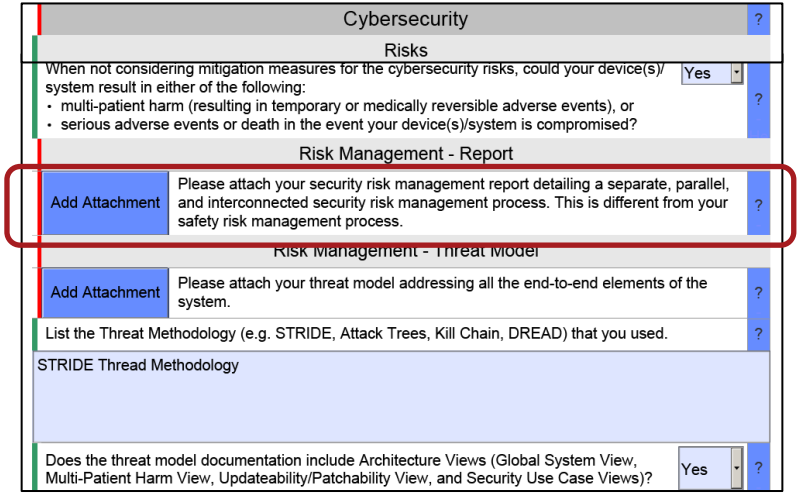
- **Biocompatibility Template Improvements**

- When selecting type of tissue contact, FDA provides specific help text and recommendations based on selection

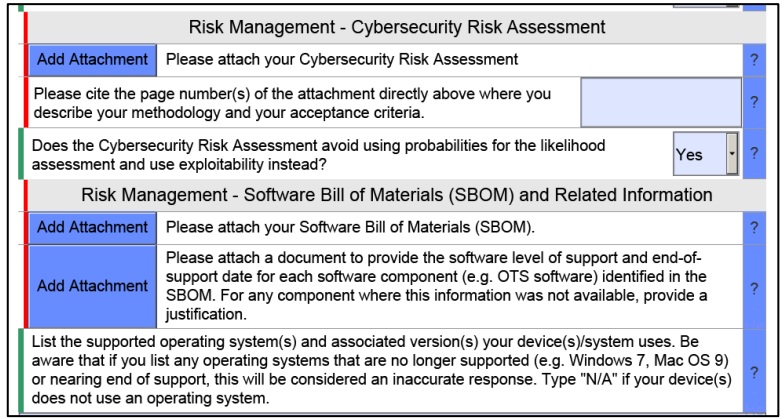


And the Template Continues to Improve – 5.0 and beyond

- **High Level of Detail required to support Cybersecurity**
  - Hint: It's all about risk!



Caution! Cybersecurity requirements in eSTAR template are very specific – ensure to read carefully to include the right risk process documents



And the Template Continues to Improve – 5.0 and beyond

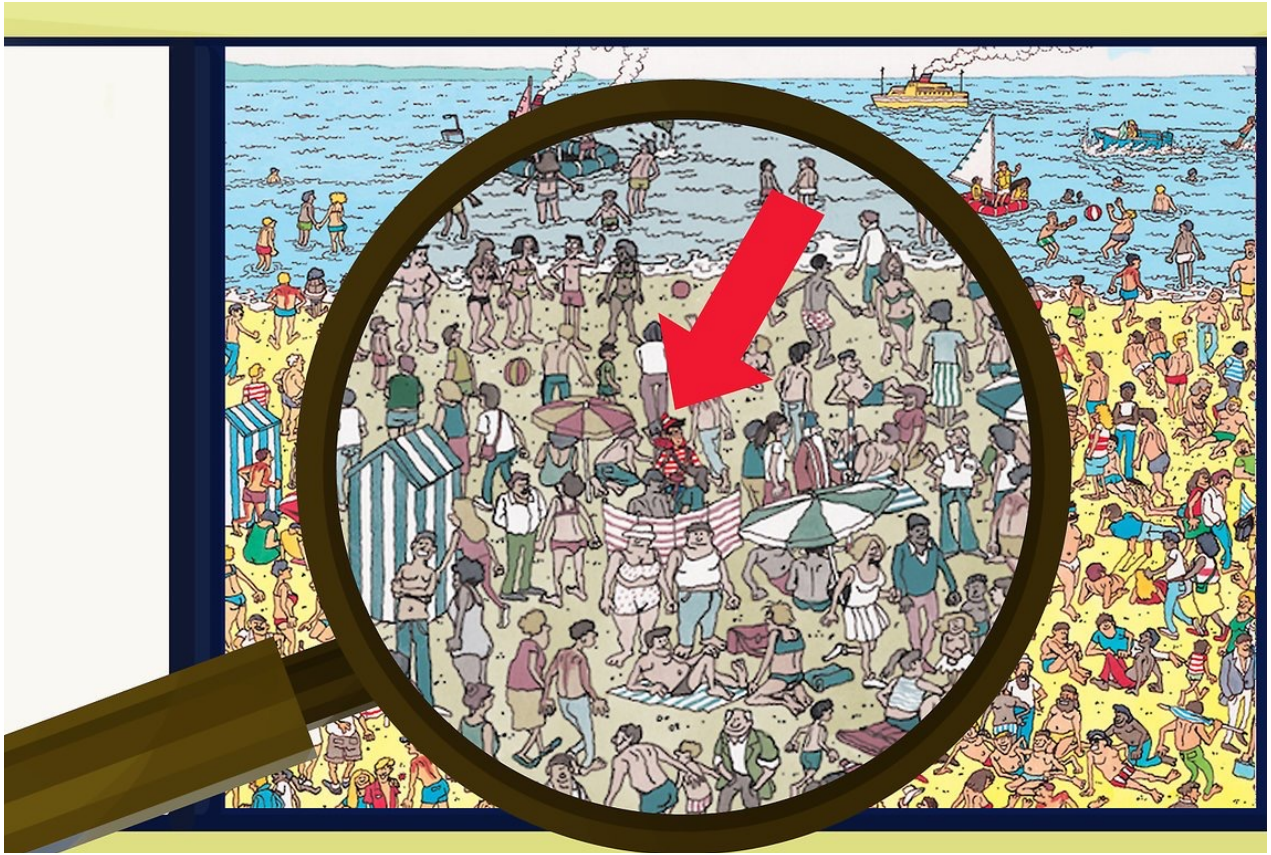
- High Level of Detail required to support Cybersecurity

Updated version 5.1 (Jan 8, 2024) template includes a greater emphasis on pointing FDA directly to correct Page Numbers

Cybersecurity Management Plan		
Add Attachment	Please attach a Cybersecurity Management Plan.	?
Please cite the page number(s) of the attachment directly above where you include the information specified in the help text to the right for all the recommended elements.		?
Please cite the page number(s) of the attachment directly above where you include a description of and justification for the time-lines to make patches on a regular cycle and out of cycle.		?

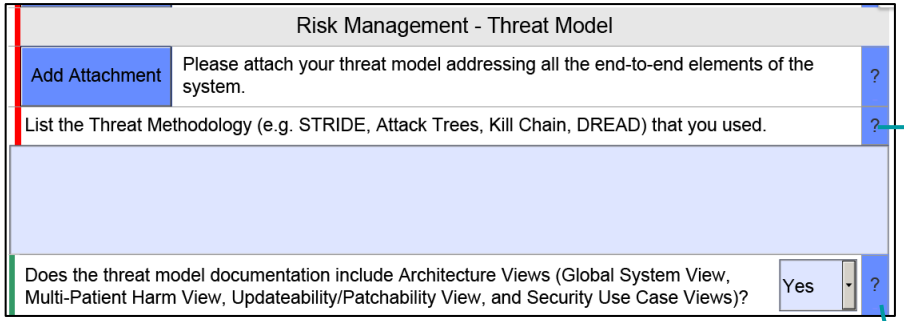
Cybersecurity Controls		
Add Attachment	Please attach information on the security controls categories included in the device.	?
Please cite the page number(s) of the attachment directly above where you addressed the following controls listed in the textbox below (e.g. "A) Authentication Controls: *Page 2*").		?
A) Authentication controls: B) Authorization controls: C) Cryptography controls: D) Code, data, and execution integrity controls: E) Confidentiality controls: F) Event detection and logging controls: G) Resiliency and recovery controls: H) Firmware and software update controls:		
Architecture Views		
Add Attachment	Please attach a document(s) that contains a Global System View, Multi-Patient Harm View, Updatability/Patchability View, and Security Use Case Views. If these Architecture Views are provided in the Threat Modeling documentation provided above, please cite where each of the Architecture Views is provided.	?
Cybersecurity Testing		
Add Attachment	Please attach a document(s) that describes the cybersecurity testing performed and the associated test reports. Cybersecurity testing includes but may not be limited to security requirement testing, threat mitigation testing, vulnerability testing, and penetration testing. If security testing was performed by a third party, please provided the original third party test report and your assessment of any findings. Alternatively, provide a justification for why particular testing was not performed.	?
Cybersecurity Labeling		
Please specifically cite the attachment(s) and page number(s) where cybersecurity information is documented in the labeling, as specified in the help text to the right for all the recommended elements. If there is separate cybersecurity labeling, attach this in the labeling section above.		?

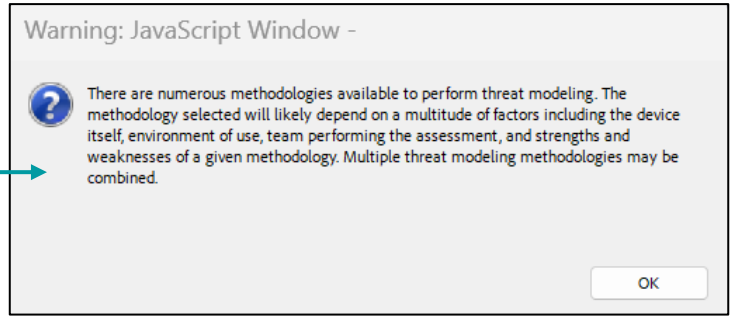
FDA is not playing Where's Waldo with your 510(k)…

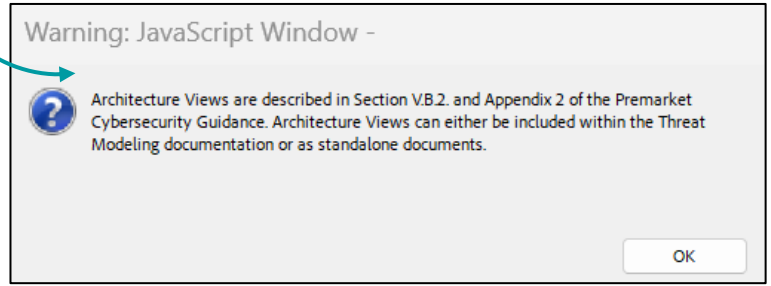


Secrets to Success: Cybersecurity

- FDA is now requesting details, details, details



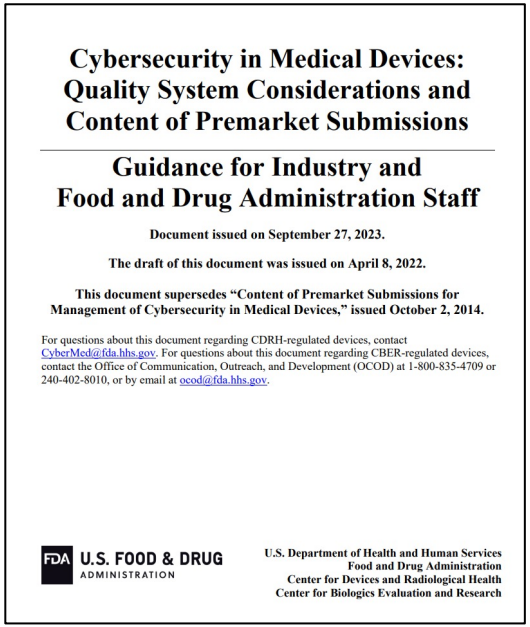




Note: Help text points to examples or related guidance documents for assistance with these sections

Secrets to Success: Cybersecurity

- Don't forget to use the new FDA Guidance (Sep 2023) as a guide



Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 27, 2023.

The draft of this document was issued on April 8, 2022.

This document supersedes "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," issued October 2, 2014.

For questions about this document regarding CDRH-regulated devices, contact CyberMed@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

Table 1. Recommended Premarket Submission Documentation

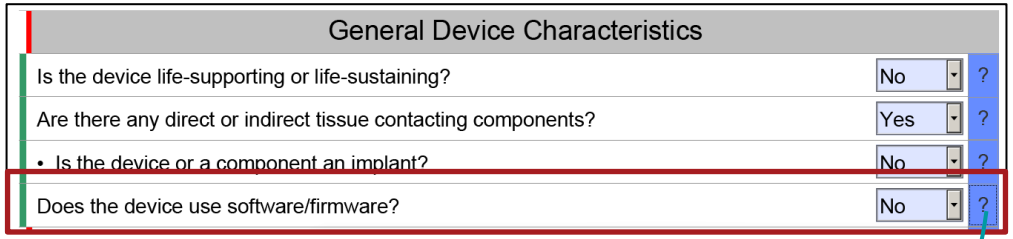
Type of Premarket Submission Documentation	Guidance Section(s)	IDE Submission*
Cybersecurity Risk Management Report	Sections V., VI.B.	Could be helpful to submit, but not specifically recommended
- Threat Model (may include Architecture Views)	Sections V.A.1., V.A.3., V.A.4., V.A.5., V.B.2., Appendix 1, Appendix 2	Could be helpful to submit, but not specifically recommended (see Architecture View recommendations)
- Cybersecurity Risk Assessment	Sections V.A.2., V.A.3., V.A.4., V.A.5., V.A.6.	Could be helpful to submit, but not specifically recommended
- SBOM	Sections V.A.4., VI.A.	Recommended
- Vulnerability Assessment and Software Support	Section V.A.4.	Could be helpful to submit, but not specifically recommended
- Unresolved Anomalies Assessment	Section V.A.5.	Could be helpful to submit, but not specifically recommended
- Traceability	Sections V.A., V.A.1., V.A.2., V.A.3., V.A.4., V.A.5, V.A.6., V.B.1., V.B.2., V.C., VI.A.	Could be helpful to submit, but not specifically recommended

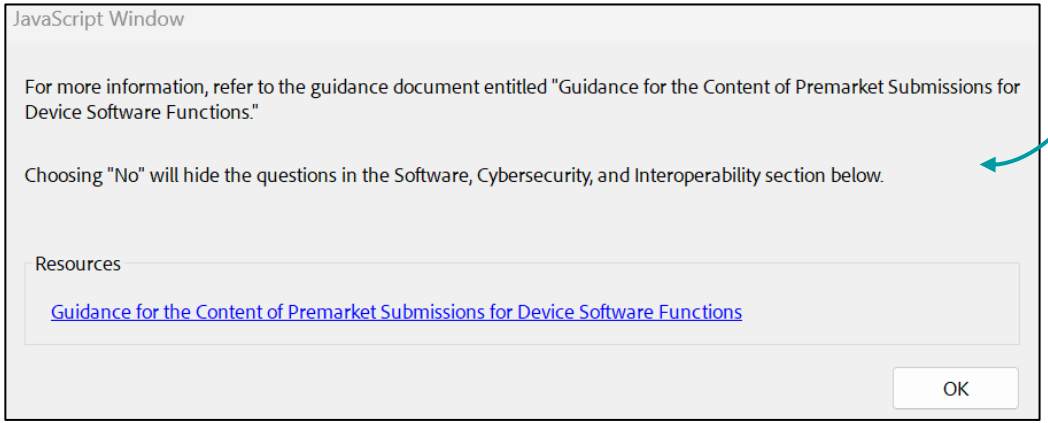
Many recommendations align exactly with eSTAR template

More Rev 5 Updates: Prevent Missing Sections

- Cross-Section Change Reminders

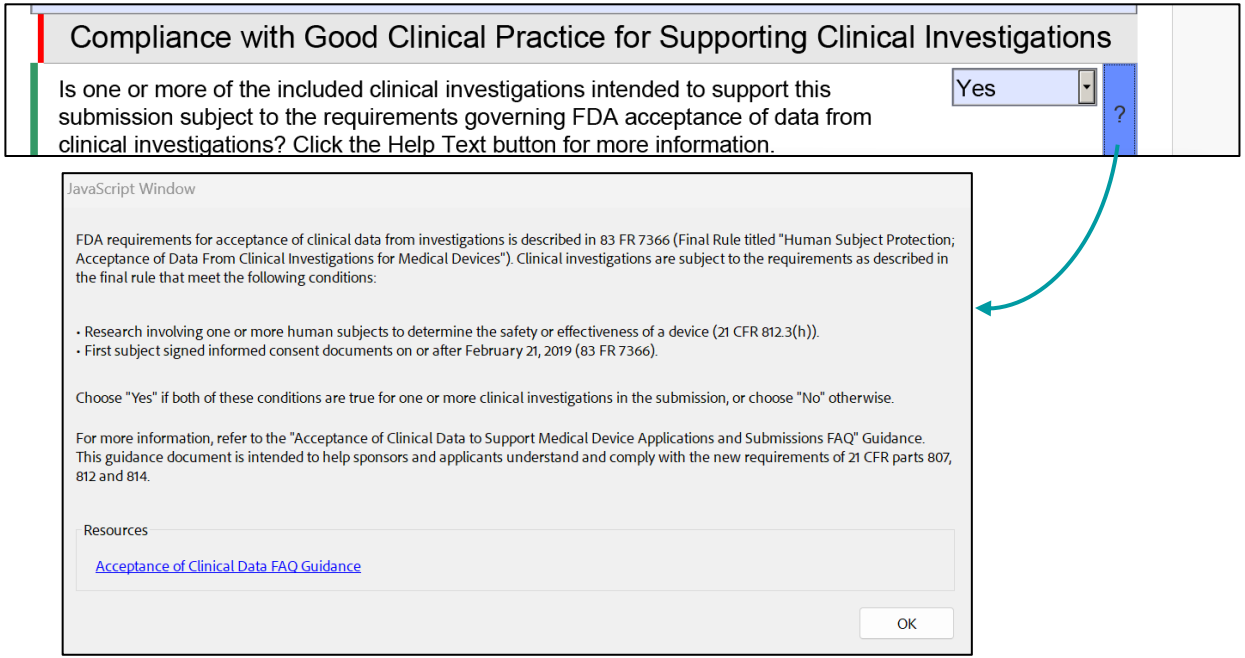
- When selecting 'No' for certain questions, the help pop-up will clarify if that means certain sections will not be available for you.





More Rev 5 Updates

- **Clinical Data Updates – for 510(k)**
  - Ensure clinical investigations supporting submission are disclosed (Help Pop-Up is informative for selection)



More Rev 5 Updates

- **Clinical Data Updates – for PMA/De Novo**
  - Significantly more data related to clinical investigations required. Ensure clinical investigations follow 21 CFR 812.

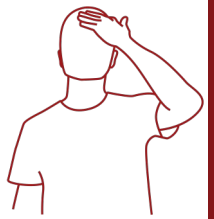
General Clinical Information	
Please specifically cite the attachment(s) and page number(s) where the following information is located. Type "N/A" if not applicable.	
Summary of the clinical investigation(s) and results	
Final versions of the clinical protocols (If performed under IDE, these should be the final FDA-approved versions of the clinical protocols, incorporating any Notices of Changes.)	
Description of study population demographics	
Description of adverse events (e.g., adverse reactions, complaints, discontinuations, failures, replacements)	
Report forms for patients who died or who did not complete the investigation (i.e., to resolve potential bias). State "N/A" only if no patients died or were discontinued.	
Statistical analyses of the clinical investigations	

Results of all analyses identified in the protocol	
Sample size/number of patients enrolled and completing the study (i.e., the number of evaluable patients at the primary endpoint time frame)	
Follow-up duration for the primary analysis	
Follow-up evaluations for the primary analysis	
Study Objectives	
Study Population/Enrollment Criteria	
Study Endpoints	
Study Design	
Hypothesis	
Effectiveness Statistical Analysis	
Safety Statistical Analysis	
Dataline listings stratified by site, then subject.	
Patient/study population match the intended use discussion	
Have clinically significant endpoints been selected explanation	
If the primary study is based on foreign clinical data, provide a justification with respect to how the data are applicable to the U.S. patient population (e.g., are the population and medical practices comparable to those in the U.S., or if not, provide a justification for why any differences would not impact the applicability of the study results to the U.S. patient population [21 CFR 814.15(a) and 814.15(b)]).	

Weaknesses

- **Be aware of:**
  - **File Size**: Processing of the submission may be delayed if the eSTAR PDF exceeds 4 GB in size or 1GB per any one file type.
  - **File Versions:** Make sure to use current version of eSTAR template for complete required content.
  - **Export/ Import:** eSTAR does have an export and import feature if you get caught between versions. However, it will not export and import attachments.
  - **Using the most updated versions of applications**: There is a JavaScript bug in certain Adobe Acrobat Pro applications that causes dynamic PDFs like eSTAR, to run **slower than normal**.

Directly from the FDA website: *This slowness bug is not present in FoxIt PDF Reader, any version of Adobe Acrobat Pro 2017, and for at least some, but not all, users of Adobe Acrobat Pro DC and the latest Adobe Acrobat Pro Windows versions. We are working with Adobe to help them resolve this bug.*



Weaknesses

- Process is still being worked out…

FDA Issues Minor Updates to Final Guidance for Electronic Submissions Template for Medical Devices 510(k) Submissions

Today, the U.S. Food and Drug Administration (FDA) issued minor updates to the final guidance: ***Electronic Submissions Template for Medical Devices 510(k) Submissions***. The updates are to support the use of the Electronic Submission Template and Resource (eSTAR) through the CDRH Portal. As of October 1, 2023, all 510(k) submissions, unless exempted, must be submitted as electronic submissions using eSTAR.

Use of eSTAR for all 510(k) submissions is part of the FDA's ongoing efforts to modernize the 510(k) Program, and implement MDUFA V and 745A(b) of the Federal Food, Drug, and Cosmetic Act.

Read More

This final guidance provides the following minor updates:

- Withdrawal requests, which have previously been submitted via email continue to be exempt from electronic submission requirements.
- While use of eSTAR will be required starting on October 1, 2023, there are currently known technical reasons that preclude electronic submission via the CDRH Portal and impacted submissions will need to be mailed to the CDRH Document Control Center.

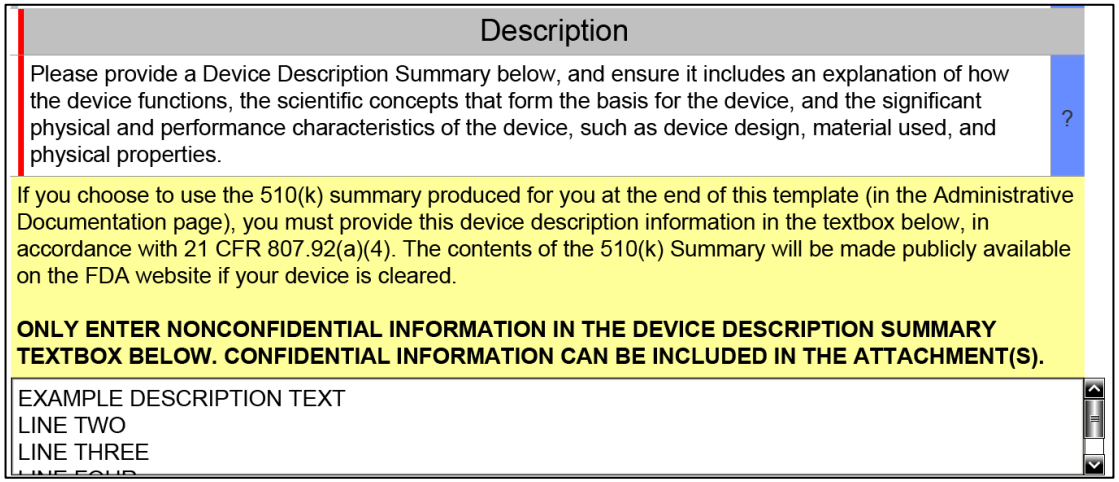
Weaknesses, cont.

- **Complications with signatures**
  - Truthful and Accuracy statement must be signed by official correspondent editing the file
    - Options for workarounds: digital signature from client/manufacturer
    - This is a concern for working with consultants
  - Official correspondent must finalize all signatures
    - Multiple signatures can be difficult

- **In practice, file collaboration likely must occur outside of eSTAR template**
  - eSTAR does not track changes
  - File sharing of the eSTAR template can be difficult
  - If you rely on iterative editing or editing with multiple people (from the manufacturer and/or consultants), using solely the eSTAR template can be complex and difficult

Weaknesses, Cont.

- **Limited Text Sections**
  - Limited space for viewing; scrolling required.
  - No formatting supported
  - Content is used to populate automatic 510(k) summary (if used)
    - DO NOT include confidential information in text boxes



Size of text boxes does not change with the amount of text added. You must scroll to get to the top/bottom of a text section

Opportunities

- **What does this mean for the future of the 510(k)?**
  - Global harmonization initiatives
  - Standardization with other submissions (similar to HealthCanada)
  - What does the harmonization plan look like beyond this eSTAR? Classification, etc.

- **Continued expansion to other submission types**
  - De novo released in October 2023
  - Pre-submissions released on June 9, 2023
  - PMA capability released on December 6, 2023
  - Other Q-submissions and 513(g)s to come

Threats

- Template crashes
- Someone in your organization made a change
- Wasted time - too much time in front of your computer waiting for program to cooperate
- Template revision changes
- Threats may be mostly to your mental health!

eSTAR S.W.O.T. Analysis Summary

STRENGTHS

- No RTA review
- Alignment with FDA templates
- Guidance doc integration
- Automation of 510(k) summary
- Completion verification
- No more standard forms

WEAKNESSES

- Challenges with file size, count and versions
- Bugs in the software app
- Signatures
- No file collaboration within eSTAR
- Limited text sections

OPPORTUNITIES

- Streamlined 510(k) – global harmonization initiatives, standardization
- Expansion to other submission types

THREATS

- Template crashes
- Wasted time
- Minor template revision changes
- Mental health

Real World Reviews

The Reviews Are In

NOW PLAYING: eSTAR!

"Little ability to tell a story or cross reference sections, redundant info and just clunky....If you modify a further section, you have to go back and redo. " *One User*

"It's a pain"
A concerned citizen

"Personally, I really enjoy it. I really love anything you can use electronically where you can't make a mistake going forward... It reminds me of Turbotax" *Some consultant*

"It's a fancier version of the eCopy checklist"
Someone who knows what he's talking about

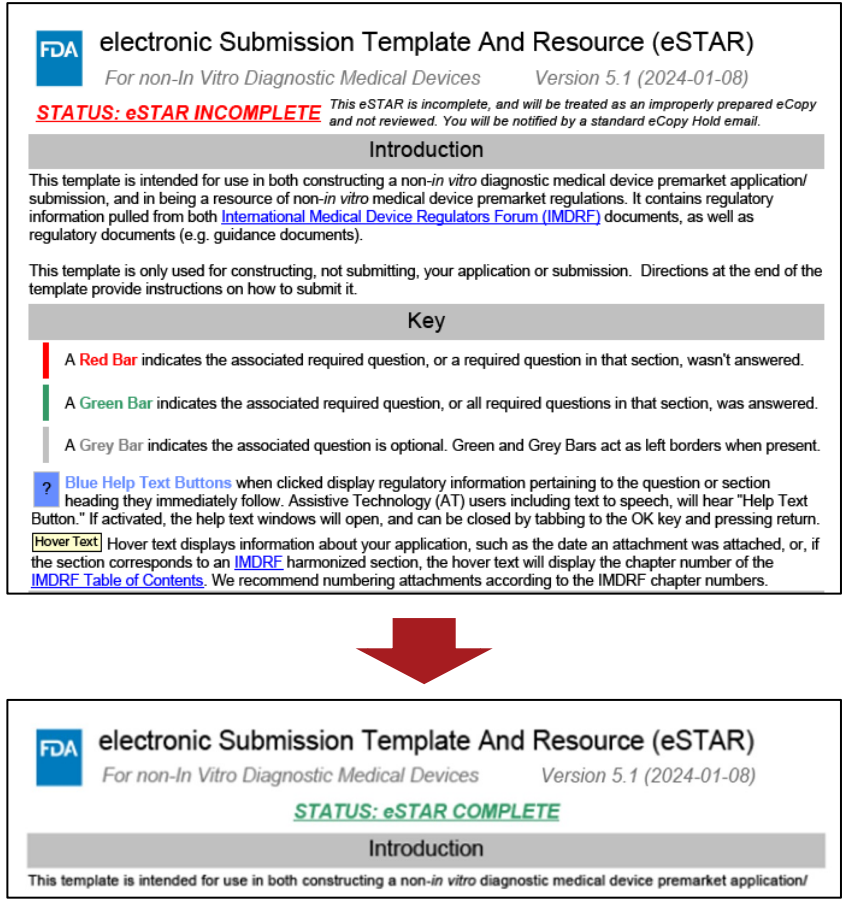
This is new to everyone

- **Even to the FDA…**
  - There may be a learning curve regarding where information is located
  - User interface on the FDA end is different
- **Currently there are no FDA-specific trainings available on CDRH Learn Portal.**
- **In the meantime, review FAQs available on the website.**
- **Another Helpful eSTAR Training:**
  - RIMSYS: eSTAR submissions

Optimizing the Process

Steps to Success

1. Download CURRENT eSTAR form from FDA
2. Populate required sections
3. Note color coordination:
   - **RED** = Required, not yet complete
   - **GREEN** = Required or optional; complete
   - **GREY** = Optional; not yet complete
4. Submit when STATUS reads **eSTAR COMPLETE**



FDA electronic Submission Template And Resource (eSTAR)

For non-In Vitro Diagnostic Medical Devices *Version 5.1 (2024-01-08)*

STATUS: eSTAR INCOMPLETE *This eSTAR is incomplete, and will be treated as an improperly prepared eCopy and 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.

Key

A Red Bar indicates the associated required question, or a required question in that section, wasn't answered.

A Green Bar indicates the associated required question, or all required questions in that section, was answered.

A Grey Bar indicates the associated question is optional. Green and Grey Bars act as left borders when present.

? Blue Help Text Buttons when clicked display regulatory information pertaining to the question or section heading they immediately follow. Assistive Technology (AT) users including text to speech, will hear "Help Text Button." If activated, the help text windows will open, and can be closed by tabbing to the OK key and pressing return.

Hover Text Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an IMDRF harmonized section, the hover text will display the chapter number of the IMDRF Table of Contents. We recommend numbering attachments according to the IMDRF chapter numbers.

FDA electronic Submission Template And Resource (eSTAR)

For non-In Vitro Diagnostic Medical Devices *Version 5.1 (2024-01-08)*

STATUS: eSTAR COMPLETE

Introduction

This template is intended for use in both constructing a non-*in vitro* diagnostic medical device premarket application/

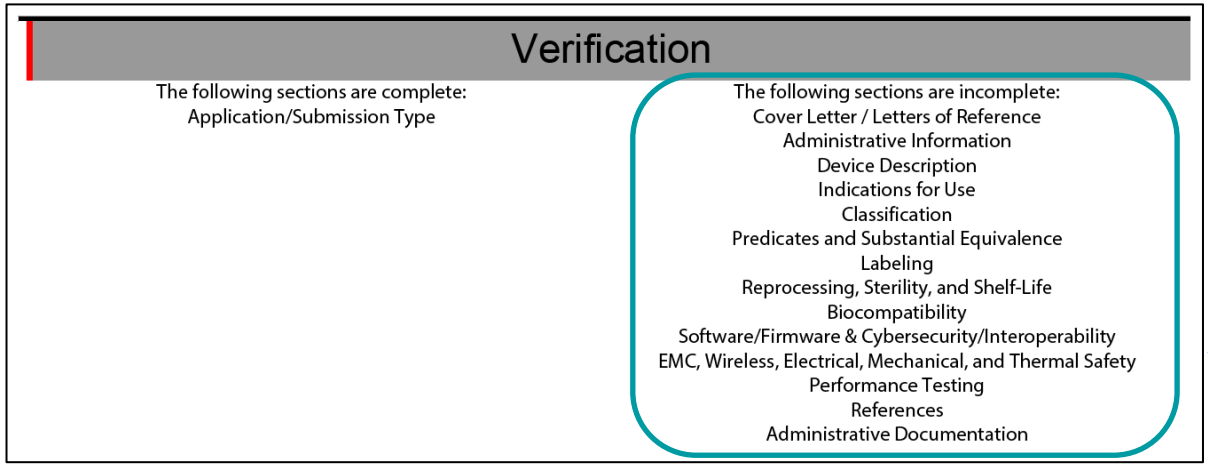
Secrets to Success

- Use the most recent template version
- Recommend preparing Word documents for team collaboration then enter in eSTAR when complete
- Utilize instructional and help text where applicable
- Use smart naming conventions to facilitate finding attachments
  - Sequential numbering
  - Title that matches attachment description in eSTAR
  - Acceptable attachment formats: PDF, Word, Excel
- ***Do not include confidential information in text boxes***

- **Save the template after every change (every attachment, every text addition, etc.) to prevent preliminary crashing!!**

Before you submit

- Use 'Verification' section at end of template to see what is missing



- Ensure status is present: ***STATUS: eSTAR COMPLETE***

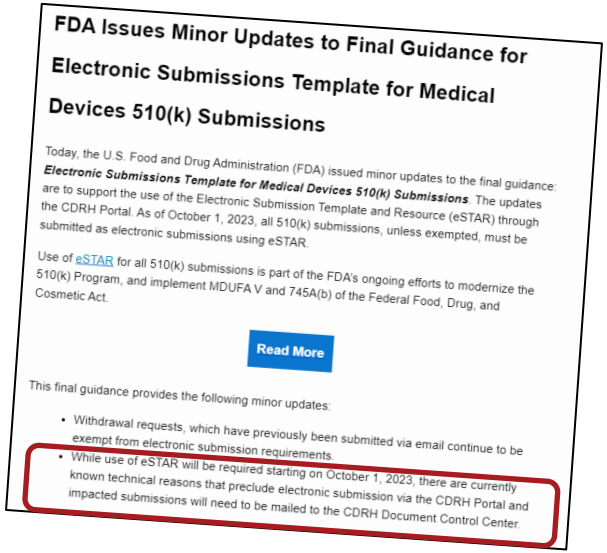
Send it electronically

▶Submit your eSTAR application online

Online: eSTAR submissions can be uploaded to CDRH Customer Collaboration Portal (CDRH CCP Portal)

Requirements:

- Signed cover letter attachment within eSTAR template
- eSTAR template with all files
- Upload to CCP and press send



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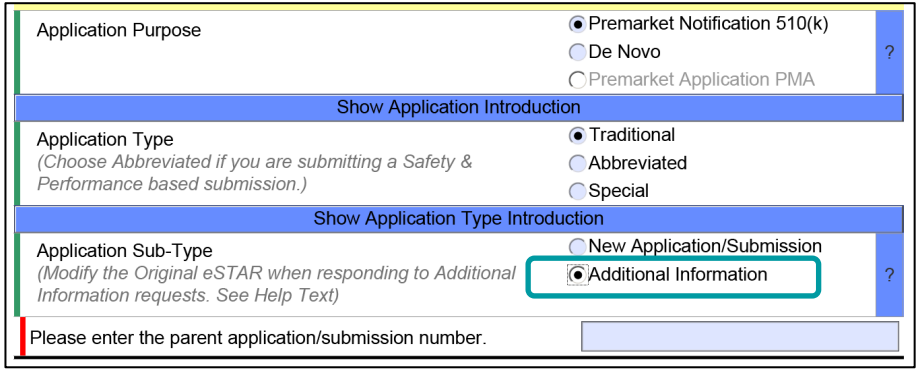
What about Requests for Additional Information?

- Option 1: Continue to submit responses to additional information (AI) requests in an eCopy format.
- Option 2: Use the eSTAR templates to respond to requests for additional information with “additional information” as the submission type.
  - The deficiency is copied into one field and response provided in another field (text box). New attachments are then included in the relevant section of the eSTAR template itself.



Note: Text boxes in the template may not be sufficient for providing lengthy explanations that require tables, figures, or formatting to keep the response clear and organized.

Related Links

- FDA eSTAR program current templates
- FDA Guidance, *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*, September 27, 2023
- FDA Guidance *Electronic Submission Template for Medical Device 510(k) Submissions*, September 22, 2022
- FDA Guidance *Format for Traditional and Abbreviated 510(k)s*, September 13, 2019
- FDA Guidance *The Special 510(k) Program*, September 13, 2019
- FDA Guidance *The Abbreviated 510(k) Program*, September 13, 2019

Free download

- Regulatory Pathway Assessment (RPA)
- Business Market Assessment (BMA)

leanraqa.com/free-guides

Questions?

Your regulatory strategy

Your regulatory submissions

Your quality systems and compliance

Your audit management

Your due diligence

Your technical support

Your grief counseling

leanRAQA

Michelle Lott, RAC

michelle@leanRAQA.com

520.275.9838

companies	industries
large	medical device
mid-sized	cosmetics
small	food
startup	dietary supplements