

# **The 510(k) Program: Overview and Program Updates**

**FDA Small Business Regulatory Education for Industry (REdI)**

July 21, 2021

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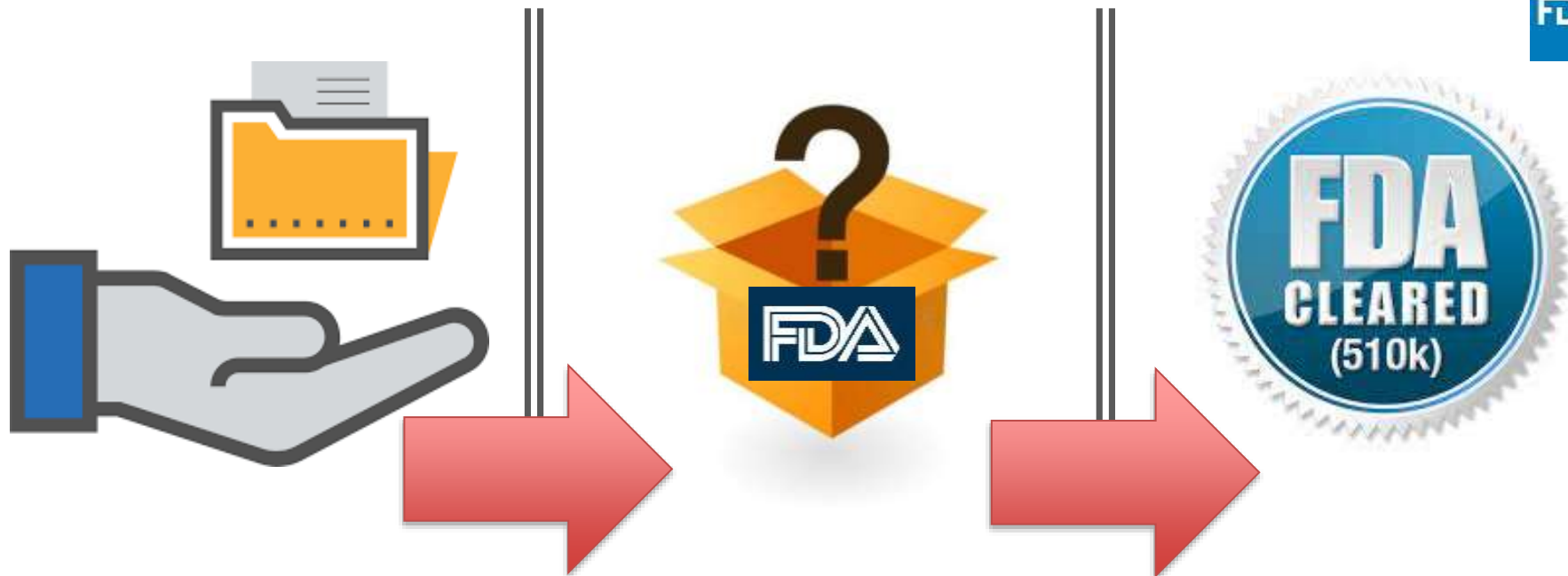
Deputy Division Director

Division of Premarket Programs

Office of Regulatory Programs

Center for Devices and Radiological Health

U.S. Food and Drug Administration



Looking Inside the FDA black box

# Learning Objectives

Describe the 510(k) Review Process

Discuss how to interact with FDA during the Review

Identify what's new: policies & pilots

# The 510(k) Review Process:

What to expect  
When to expect it

# The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

## Guidance for Industry and Food and Drug Administration Staff

Document issued on: July 28, 2014

The draft of this document issued on December 27, 2011.

This document supersedes FDA's Guidance on the CDRH Premarket Notification  
Review Program, 510(k) Memorandum K86-3, dated June 30, 1986.

For questions for the Center for Devices and Radiological Health regarding this document, contact the  
Premarket Notification (510(k)) Section at 301-796-5640.

For questions for the Center for Biologics Evaluation and Research regarding this document, contact the  
Office of Communication, Outreach and Development at 1-800-335-4709 or 240-402-7800.



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

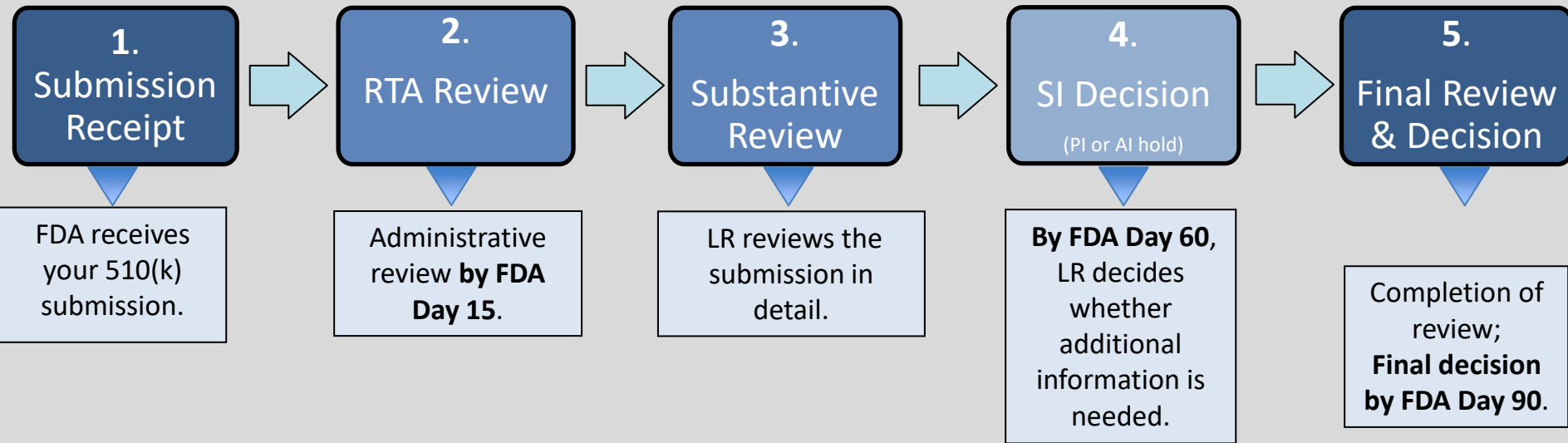
## Guidance Scope

- 510(k) Decision Making Process
- 510(k) Review Standard
  - Predicate Device
  - Intended Use
  - Technological Characteristics
  - Additional Information Requests

Also check for device-specific  
guidance & X-cutting guidance docs

- e.g., Contact Lenses guidance
- e.g., Sterility Guidance, Biocompatibility Guidance

# 510(k) Process Overview



## Acronyms:

RTA = Refuse to Accept

LR = Lead Reviewer

SI = Substantive Interaction

PI = Proceed Interactively

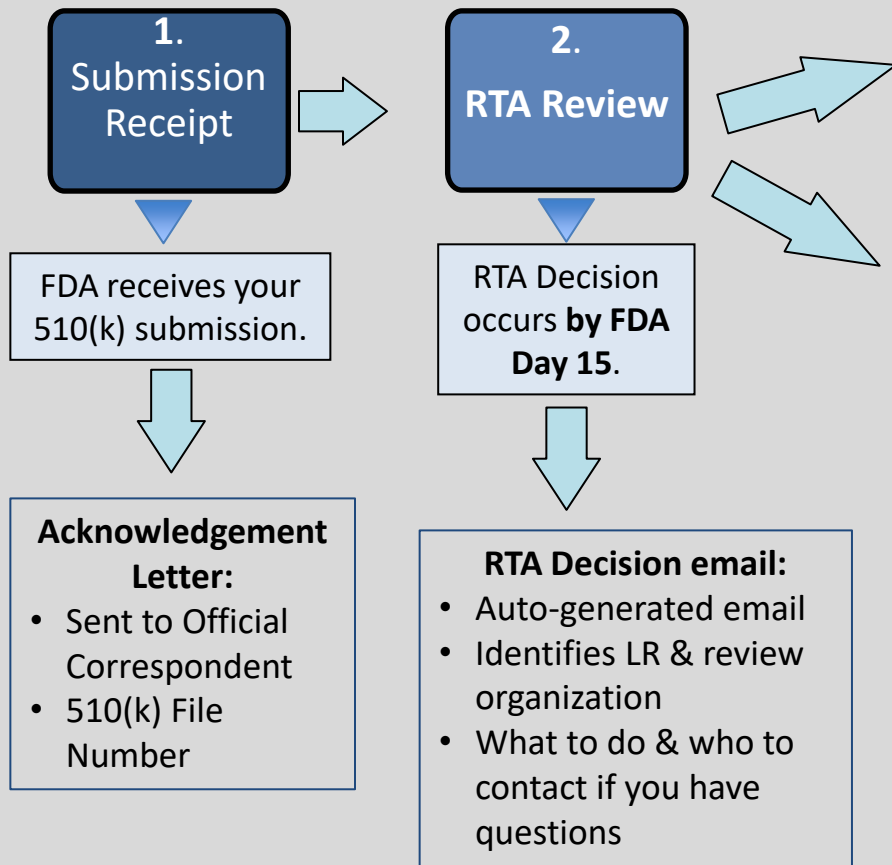
AI = Additional Information

[“FDA and Industry Actions on Premarket Notification \(510k\(k\)\) Submissions: Effect on FDA Review Clock and Goals”](#) Guidance  
For Industry and FDA Staff

## Interacting with FDA during the 510(k) Review:

- Ways to Interact at each review milestone
- Resources and Tips

# RTA Review Overview



## RTA Accept:

- FDA review clock continues
- Substantive Review Begins
- LR may request information interactively

## RTA Not Accepted:

- FDA review clock stops
- Submitter receives completed checklist
- Submitter responds w/ missing info w/in calendar 180d
- RTA review conducted again

[Refuse to Accept Policy for 510\(k\)s:  
Guidance for Industry and FDA Staff](#)

# Tips for Responding to RTA



- Include the reviewer's checklist & include page/section numbers where response can be found
- Provide a rationale for why a missing item is not relevant



- Resubmit all prior information
- Make changes to the device or indications

# RTA Addendum



## What Is An Observation?

Issue noted during administrative review that doesn't determine acceptability of submission, but would result in a deficiency during substantive review

(Examples: Missing a necessary performance test, or results from a performance test appear deficient)



### What It Is

- Early notification of “observations” made during initial RTA review
- An opportunity to address issues likely to arise during substantive review



### What It is Not

- Substantive review of submission
- Does not replace an additional information hold
- An official request for additional information
- A delay in RTA review or decision

# RTA Addendum: Where to Find it, What to Do



The image shows a software interface for RTA Addendums. On the left, an 'Attachments' panel lists a file named 'XXXXXXXX.RTA Checklist Addendum.pdf'. A red box highlights a paperclip icon in the toolbar, and a red arrow points to the file name. The main area displays the '510(k) Acceptance Checklist' from the FDA. The form includes fields for '510(k) #', 'Date Received by DCC', 'Lead Reviewer', 'Center', 'Office', and 'Division'. Under the 'Decision' section, there are radio buttons for 'Accept' and 'Refuse to Accept'. The 'Refuse to Accept' option is selected. Below this, a red box highlights the question 'Is an Addendum attached?' with 'Yes' selected. A yellow box contains the text 'Click paperclip icon on the left panel'. At the bottom, a note states: 'Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means element during the RTA review and that the element will be assessed during substantial equivalence review.' A footer note says: 'IMPORTANT - Many checklist elements include additional details regarding information to address the...'

Attachments

Name

XXXXXXXX.RTA Checklist Addendum.pdf

Department of Health & Human Services  
Food and Drug Administration

FDA

Contains Nonbinding Recommendations

## 510(k) Acceptance Checklist

Not for use with Third Party 510(k)s

Choose Submission Type: ☒ Traditional ☐ Abbreviated ☐ S

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review. FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: XXXXXXXX Date Received by DCC: [Redacted]

Lead Reviewer: [Redacted]

Center: [Redacted] Office: [Redacted] Division: [Redacted]

**Decision:**

☐ Accept. If Accept, notify submitter.

☒ Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist with the response.

**Is an Addendum attached?:** ☒ Yes ☐ No

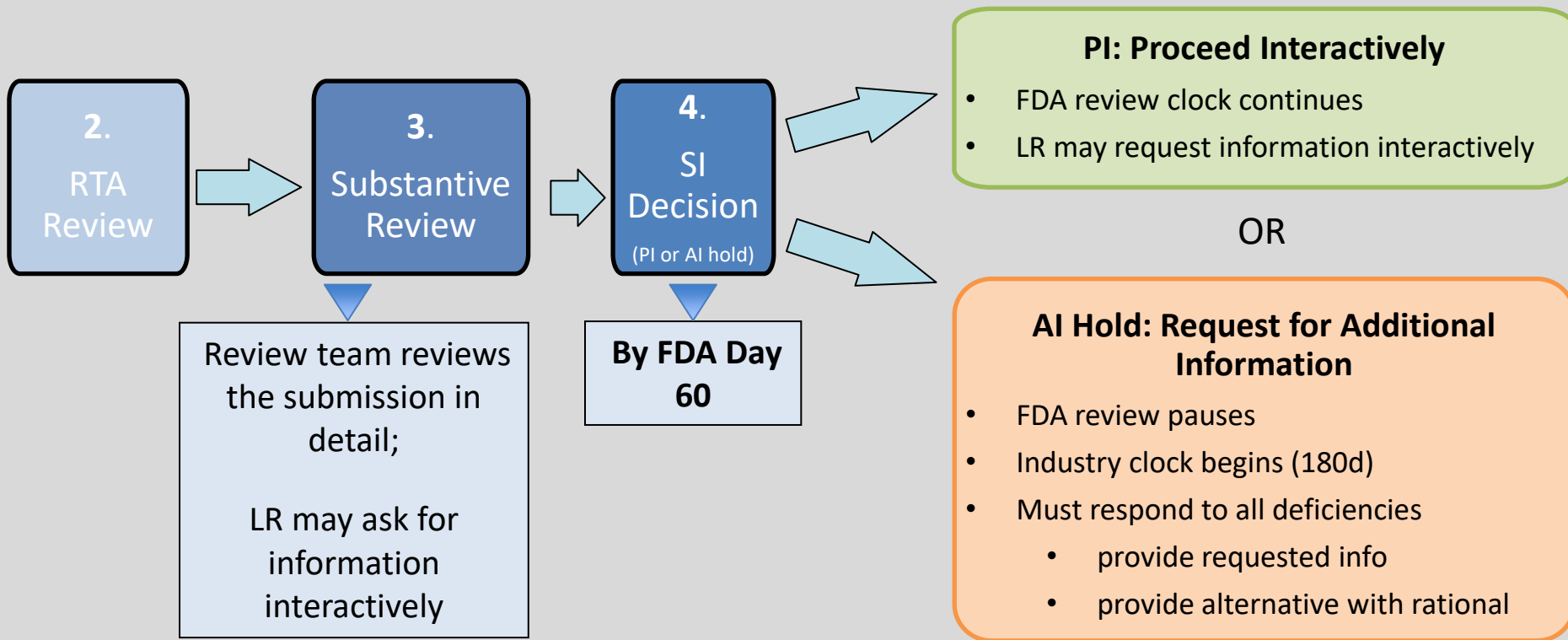
Click paperclip icon on the left panel

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the element will be assessed during substantial equivalence review.

**IMPORTANT** - Many checklist elements include additional details regarding information to address the...

- Must respond to missing RTA items
- Optional response to addendum items

# Substantive Review Overview



# Day-10 Call



**Description:** You can request a call with FDA that occurs within ten (10) days after issuance of an AI letter. The purpose of the call is to address clarification questions pertaining to the deficiencies in the letter.



## What It Is

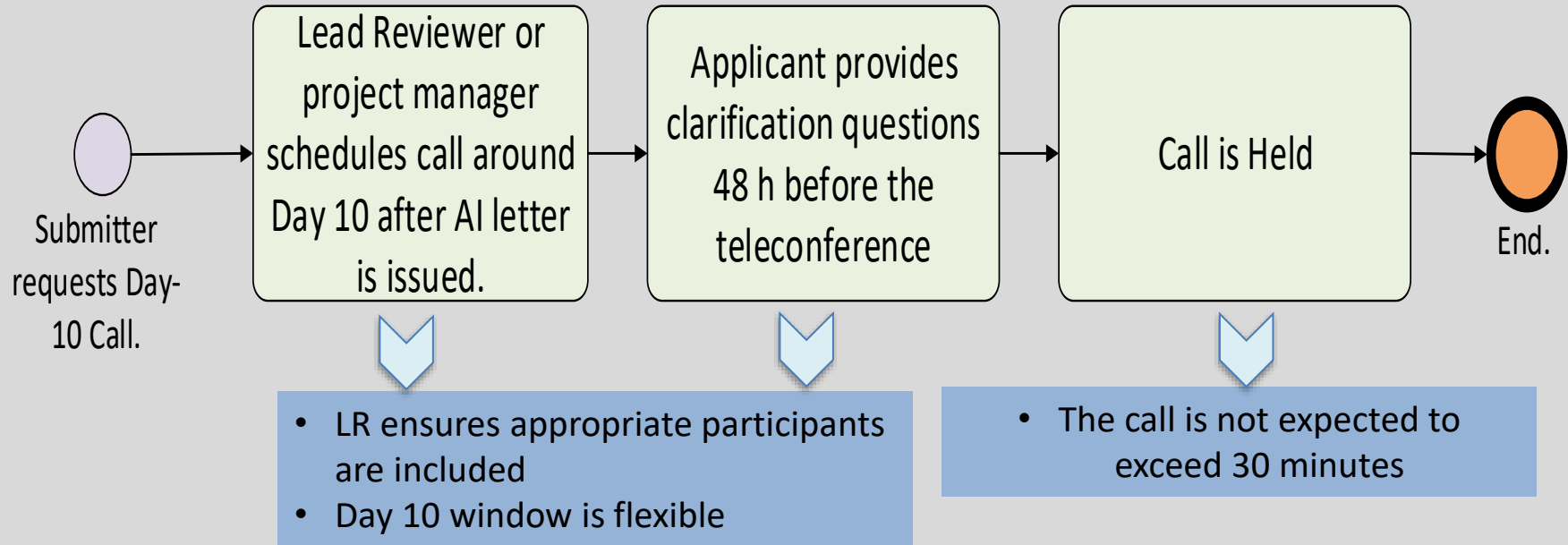
- Teleconference
- Confirmation that submitter understands deficiencies in the letter
- Can be used to determine whether a Submission Issue Request is needed.



## What It Is Not

- Review of additional information provided by submitter
- Discussion of issues unrelated to deficiencies in the AI letter
- A Submission Issue Request meeting

# Day-10 Call: Process Flow



# Least Burdensome (LB) Flag



**Description:** You feel that deficiency(s) do not adhere to the least burdensome principles and request a discussion and review with a manager



## What It Is

- Opportunity to address LB discrepancies in an AI letter
- Opportunity for submitters to address situations when they feel they are being held to a different standard



## What It Is Not

- An Appeal Meeting
- Change to 180 Response deadline

# Resources: where to go and when

OHTs

Lead  
Reviewer  
(LR)

Assistant  
Director  
(AD)

Start here  
for  
questions  
related to  
your  
specific  
file/device

ORP

Division 1:  
510(k) Team

510k\_Program  
@  
fda.hhs.gov

Start here  
for  
questions  
related to  
process &  
policy

# What would you do?



**I think one of the deficiencies asked is not relevant for my device. The best practice is...**

1. Email the CDRH Ombudsman & the OHT Director to get their opinion
2. Email the LR and ask for a 10d call to clarify the rationale for the deficiency. I can escalate and throw the LB Flag if I still disagree
3. Respond to the deficiency with the requested info

# Knowledge Check



**If your submission is not accepted for review (RTA reject), you will always receive the checklist and the RTA addendum**

1. True
2. False

# What's new in 510(k)

## New Program

- Safety and Performance Based Pathway

## Pilots

- ASCA
- eSTAR
- Customer Collaboration Portal

[www.fda.gov/medical-devices/premarket-notification-510k/510k-program-pilots](http://www.fda.gov/medical-devices/premarket-notification-510k/510k-program-pilots)

# Safety and Performance (S&P) Based Pathway

## What is it?

New voluntary 510(k) pathway:

- For well understood Class II devices that meet specified performance criteria
- Performance criteria outlined in Guidance Document

## What's the Same?

- 510(k) MDUFA user fee and eCopy requirements
- Review Process and Timelines
- No change to the SE decision making matrix

# S&P Pathway: Why Should I Use It?



- Each device guidance outlines necessary performance tests
  - Takes guess work out of applicable performance testing
  - Creates more efficient review
  - Opportunity for industry to provide input

More info [www.fda.gov/medical-devices/premarket-notification-510k/safety-and-performance-based-pathway](https://www.fda.gov/medical-devices/premarket-notification-510k/safety-and-performance-based-pathway)

# Accreditation Scheme for Conformity Assessment (ASCA) Pilot



## What is it?

- Voluntary program
- Partnership with FDA, industry, and test facilities
- Leverages recognized consensus standards to streamline device premarket review
- Enhances FDA's confidence in test methods and results

## Why use it?

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

# QUIK and eSTAR Pilots



## "Quik" Review Pilot

### Quality in 510(k) Review Pilot

- eSubmitter for certain devices
- Pilot ended May 2021
- Outcomes of Pilot:
  - Produced well organized submissions
  - Facilitated efficient review
  - Some features incorporated into eSTAR

## eSTAR Pilot

### eSTAR Pilot Program

- Started February 2020
- Voluntary use; for any device
- Submission Preparation Tool
  - Dynamic PDF template
    - Guided submission preparation
    - Complements the SMART review template used by review staff
- Still need to submit eCopy via DCC
- No RTA review; technical hold if not filled out correctly

# Customer Collaboration Portal Pilot



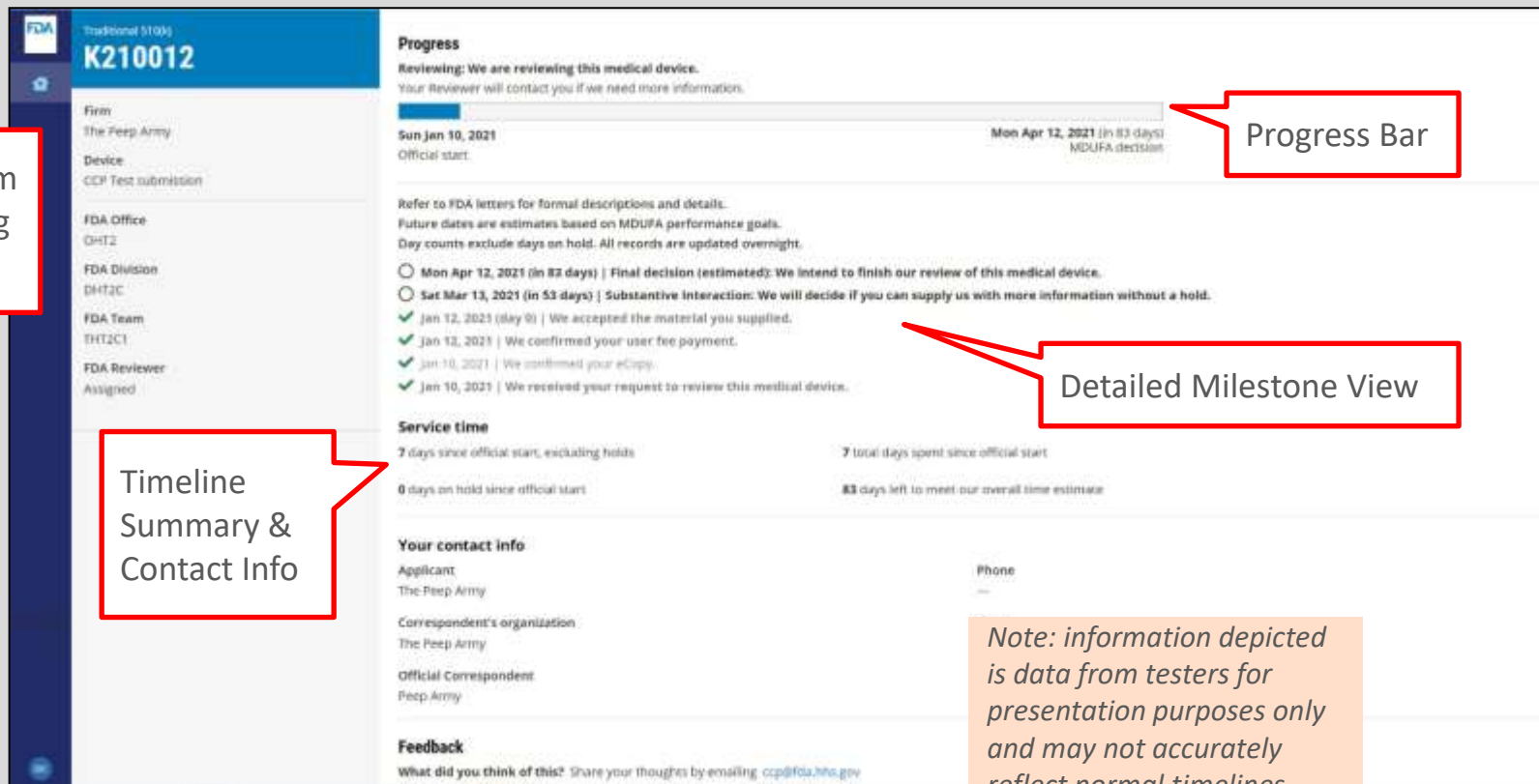
CCP Pilot

## Progress Tracker Pilot

- Pilot started June 2021
  - 100 industry participants
  - [Progress Tracker Pilot web page](#)
  - Realtime Status updates
- Future:
  - Interact with LR through portal
  - All premarket submission types

The screenshot displays the 'Progress Tracker Pilot' web interface. On the left, a sidebar lists submission details: 'Traditional 510(k)', 'K210000', 'Firm', 'Company name', 'Device', 'Device trade name', 'FDA Office' (DHT6), 'FDA Division' (DHT6B), 'FDA Team' (THT6S2), 'FDA Reviewer' (Assigned), and 'No items'. The main content area is titled 'Progress' and shows a progress bar for 'Processing: We are processing your request to review this medical device.' with a timeline from 'Thu Jul 8, 2021' to 'Wed Oct 6, 2021 (in 86 days)'. Below the progress bar, there are instructions to refer to FDA letters for formal descriptions and details, and a list of events: 'Wed Oct 6, 2021 (in 86 days) | Final decision (estimated): We intend to finish our review of this medical device.', 'Mon Sep 5, 2021 (in 56 days) | Substantive Interaction: We will decide if you can supply us with more information without a hold.', 'Fri Jul 23, 2021 (in 11 days) | Acceptance decision: We will decide if the material you supplied is enough for us to start our review.', 'Jul 8, 2021 | We confirmed your user fee payment.', 'Jul 8, 2021 | We confirmed your eCopy.', and 'Jul 8, 2021 | We received your request to review this medical device.' The 'Service time' section shows '4 days since official start, excluding holds' and '4 total days spent since official start'. The 'No items' section shows '0 days on hold since official start' and '86 days left to meet our overall time estimate'. The bottom section is titled 'Your contact info'.

# Progress Tracker: Industry View



Data pulled from internal tracking systems

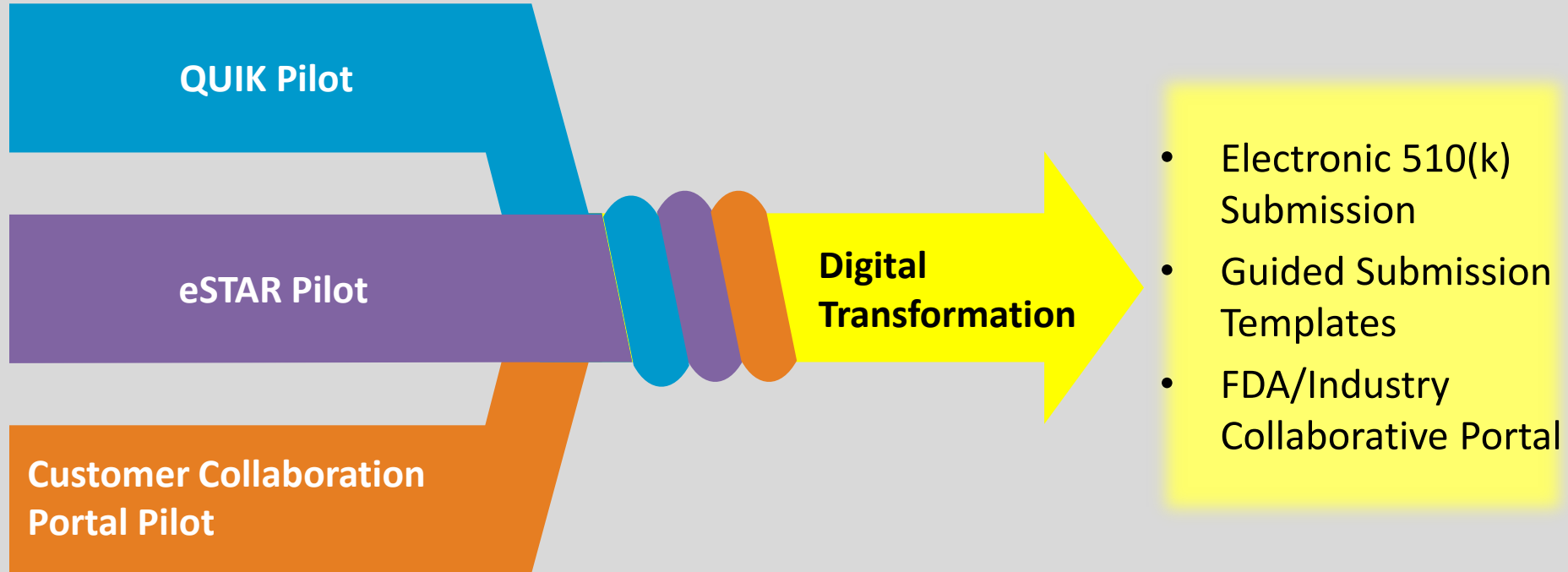
Timeline Summary & Contact Info

Progress Bar

Detailed Milestone View

*Note: information depicted is data from testers for presentation purposes only and may not accurately reflect normal timelines*

# Digital Transformation: 510(k)



# Resources



| Slide Number | Cited Resource   | URL  |
|--------------|--|--|
| 5            | The 510(k) Program: Evaluating Substantial Equivalence   | <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k">www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k</a>   |
| 6            | FDA and Industry Actions on Premarket Notification (510k(k)) Submissions: Effect on FDA Review Clock and Goals | <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals">www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals</a> |
| 8            | Refuse to Accept Policy for 510(k)s  | <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks">www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks</a>   |
| 15           | The Least Burdensome Provisions: Concept and Principles  | <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles">www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles</a>   |
| 16           | CDRH Management Directory  | <a href="http://www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization">www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization</a>   |

# Resources, cont'd



| Slide Number | Cited Resource                               | URL  |
|--------------|--|--|
| 20           | 510(k) Pilots Web page                       | <a href="http://www.fda.gov/medical-devices/premarket-notification-510k/510k-program-pilots">www.fda.gov/medical-devices/premarket-notification-510k/510k-program-pilots</a>   |
| 22           | Safety and Performance Based Pathway Program | <a href="http://www.fda.gov/medical-devices/premarket-notification-510k/safety-and-performance-based-pathway">www.fda.gov/medical-devices/premarket-notification-510k/safety-and-performance-based-pathway</a>   |
| 23           | ASCA Pilot Web page                          | <a href="http://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca">www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca</a>               |
| 23           | ASCA Pilot program guidance                  | <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program">www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program</a> |
| 25           | Progress Tracker Pilot                       | <a href="http://www.fda.gov/medical-devices/industry-medical-devices/progress-tracker-premarket-submissions">www.fda.gov/medical-devices/industry-medical-devices/progress-tracker-premarket-submissions</a>   |

# Questions



