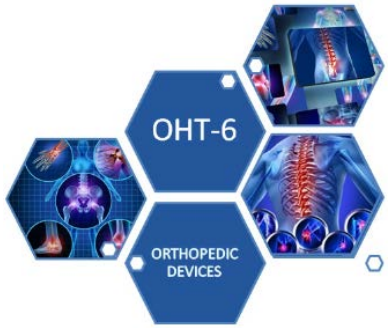


U.S. FOOD & DRUG ADMINISTRATION

510(k) Refuse-to-Accept Checklist: Why Is My Submission Not Good Enough?

Brittany Ferrell, BS

Lead Reviewer, Extracolumnar Spinal Devices Team

DHT6B: Division of Spinal Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

RTA Process

PURPOSE

Reward complete submissions;

Efficient use of reviewer resources;

Reduce number of review cycles and total time to final decision

WHAT IT IS

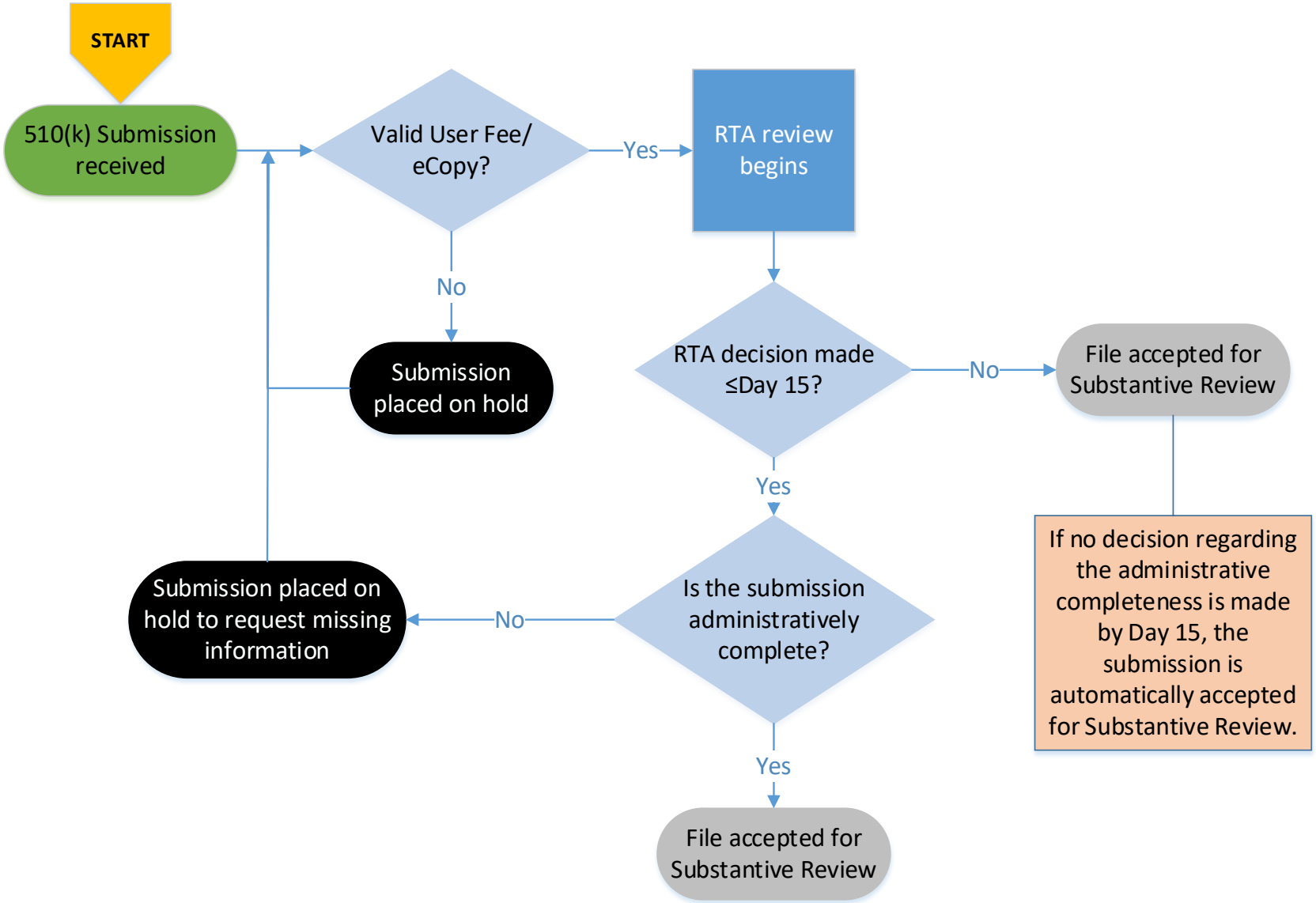
Objective tool to understand key components of complete submission

WHAT IT IS NOT

An evaluation of adequacy of content or rationale

Refuse to Accept Policy for 510(k)s guidance

510(k) RTA Process Overview



RTA Checklist-Best Practice

Fill out the RTA Checklist and provide page numbers where RTA elements are located

[Refuse to Accept Policy for 510(k)s]

Administrative

Identifying prior submissions is the most common item missed

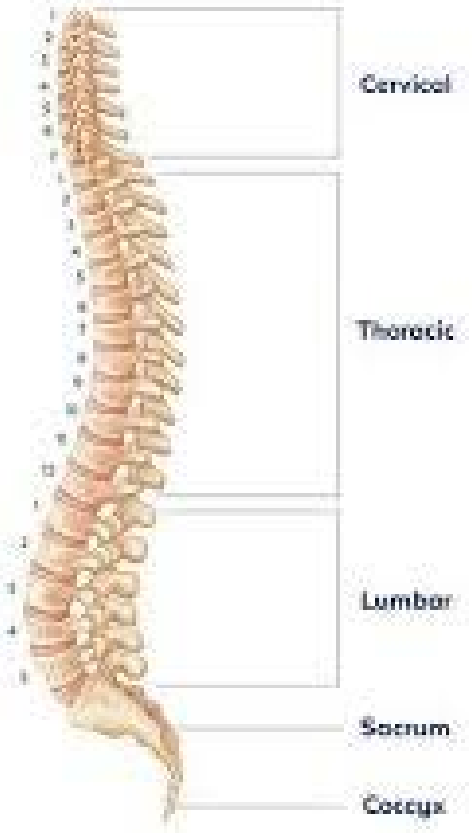
To meet criterion:

- Specifically state that there are no prior submissions for the subject device, or
- Reference prior submission(s) by file number and **state where in the submission all previous feedback has been addressed**

Device Description

A complete Device Description should include the following:

- A written device description and images of all subject components and/or modifications
- Complete dimensioned engineering drawings
- An all-inclusive list of components for both subject and any previously cleared devices



Substantial Equivalence

The substantial equivalence section should:

- Identify a predicate device
- Compare indications for use
- Compare technological features (e.g., design features, dimensions)

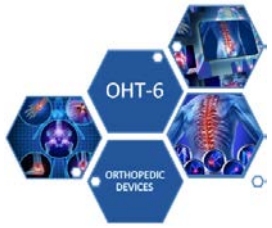
The identified primary predicate should be consistent throughout the submission

Proposed Labeling

The Labeling may include:

- Outer Package Label
- Instructions for Use/Package Insert
- Surgical Technique Manual

The Indications for Use in the Labeling should be identical to the Indications for Use form and 510(k) Summary

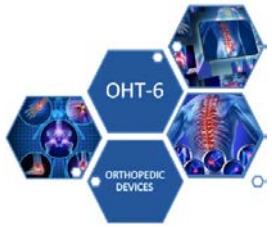


Sterilization and Shelf-Life

Specify device as Sterile and/or Non-sterile

Sterile Devices
Sterilization method including dose for radiation
Description of method to validate the sterilization parameters (e.g., full citation of FDA-recognized standard)
Sterility Assurance Level
Description of packaging
Shelf life/expiration date
Methods that will establish packaging & device performance is maintained for entire shelf life

Non-Sterile Devices
Cleaning/disinfection method
Sterilization parameters
Shelf life is not applicable
Statement why performance data is not needed to maintain device performance



Biocompatibility

- Specify the material(s) and standards

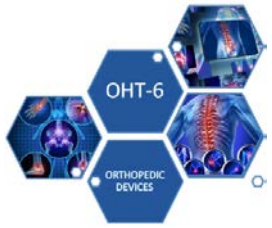
ASTM F136

- Provide rationale for why biocompatibility testing is not needed (e.g., material(s) and manufacturing processes are **identical** to a predicate)

- Highlight any changes to the biocompatibility

CDRH Biocompatibility Guidance

ASTM F1537



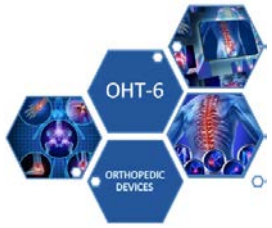
Performance Data

Test Report Summary

- Tests Performed
- Rationale for worst-case construct/components
- Methodology
- Results Summary
- Discussion and Conclusion

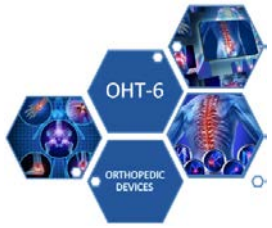
Complete Test Reports

- Test Performed
- Worst-Case Construct
- Methodology
- Results Tables
- Images of Test Set-Ups
- Images of Failure Modes
- Loading Curves Graphs
- Discussion and Conclusion



Non-Applicable Sections

If any section does not apply to the subject system (e.g., electrical or software), please note this in the submission



RTA Checklist for Specials

Design Control Activities Summary

- Risk Analysis Table
  - Device Modification
  - Risks
  - Verification Activity
  - Acceptance Criteria
  - Results of Verification

- Signed Declaration of Conformity

Labeling

- Redline or highlight all changes made to the labeling, or

- Statement that no changes were made to the labeling

RTA Addendum

WHAT IT IS

- An attachment to the RTA checklist embedded into the PDF
- Early notification of "observations" made during the initial RTA review
- An opportunity to address issues interactively during substantive review

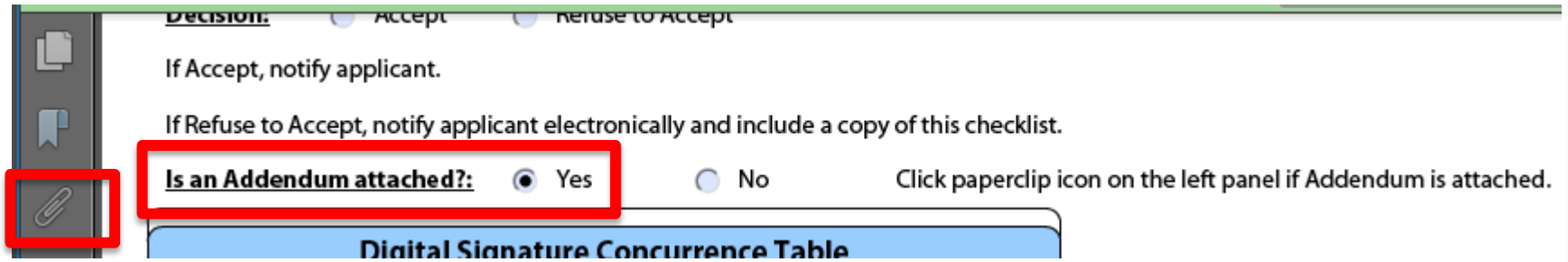
WHAT IT IS NOT

- Substantive review of the submission
- In place of an additional information hold
- An official "ask" for additional information
- A delay in the RTA review or decision

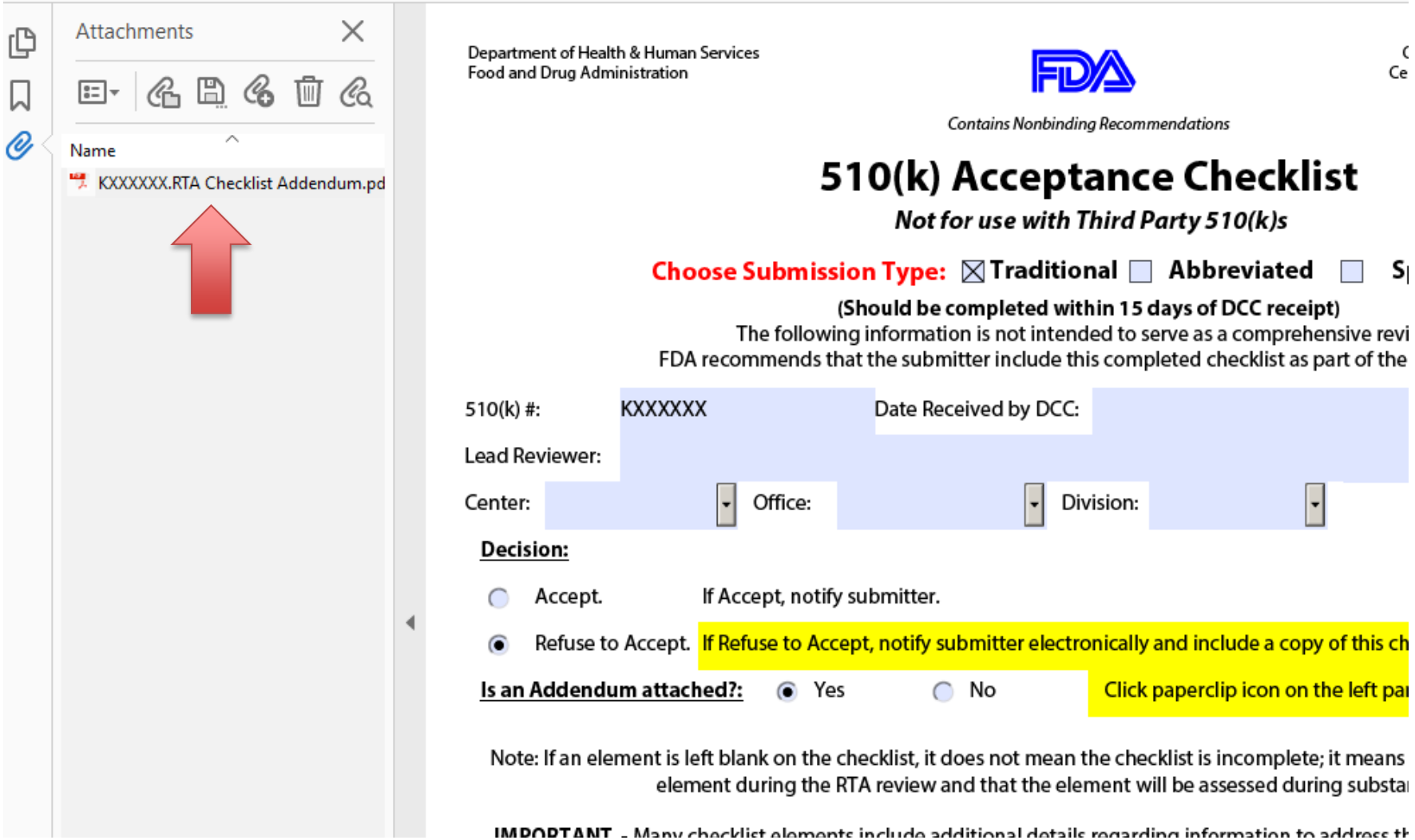
WHAT IS AN OBSERVATION?

Issue noted during the administrative review that does not determine the acceptability of a submission but would result in a deficiency during substantive review. (Example: Missing a required animal or engineering test.)

WHERE DO I FIND IT?



RTA Addendum Continued



Closing Tips and Best Practices

- Proofread final submission
  - Ensure consistency throughout submission
  - Ensure primary contact information is correct and identify an alternate contact

- Contact reviewer if clarification is needed

If you do not receive an RTA decision within 16 calendar days of your original submission, email 510(k) staff for a status check of your 510(k) application. 510K_Program@fda.hhs.gov

Thank You!

FDA U.S. FOOD & DRUG ADMINISTRATION