

X-Ray Systems: Third Party Review

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What to Know Before You Start

- Scientific understanding of x-ray systems
- “Evaluating Substantial Equivalence” guidance
[The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\]](#)
- Regulations, device-specific guidance documents and standards for x-ray systems

Key X-Ray Standards and Guidances

IEC 60601-2-54

Medical electrical equipment –
Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

IEC 62220-1-1

Medical electrical equipment – Characteristics of digital X-ray imaging devices –
Part 1-1: Determination of the detective quantum efficiency - Detectors used in radiographic imaging

Guidance

- [Guidance for the Submission of 510\(k\)s for Solid State X-ray Imaging Devices](#)
- [Content of Premarket Submissions for Management of Cybersecurity in Medical Devices](#)
- [Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices](#)
- [Pediatric Information for X-ray Imaging Device Premarket Notifications](#)
- [Radio Frequency Wireless Technology in Medical Devices](#)

Learning Objectives

Understand

Essential elements in review and documentation of 510(k)s for x-ray systems

Know

Relevant regulations, guidances, standards and terminology

Identify

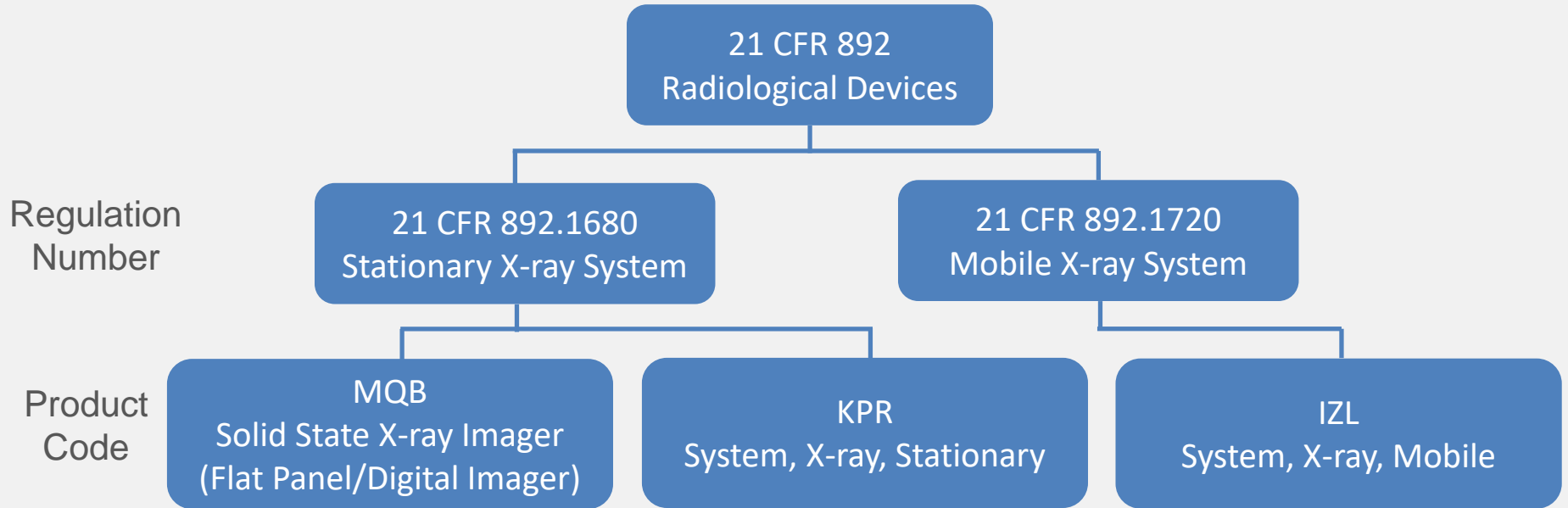
Potential premarket review items important to x-ray systems

Our New Device

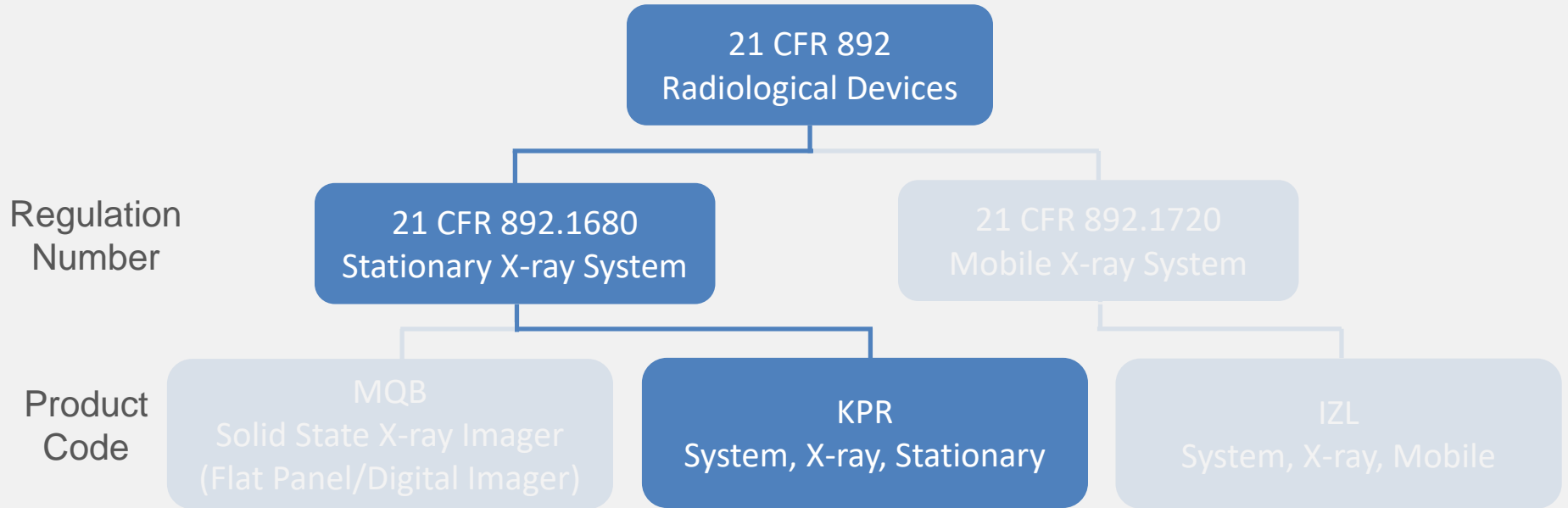


- New stationary x-ray system
- Intended for adults and pediatrics
- Key Features:
 - Generator
 - X-ray tube
 - Wireless detector
 - Software: Autogrid, Low Dose Protocol (LDP)
 - Claims: Image quality, Dose reduction

Classification Regulation and Product Codes for X-ray Systems



Classification Regulation and Product Codes for X-ray Systems



Steps to Determine Substantial Equivalence

Highlight & Document

Essential components of the submission

Use Device Specific Documents

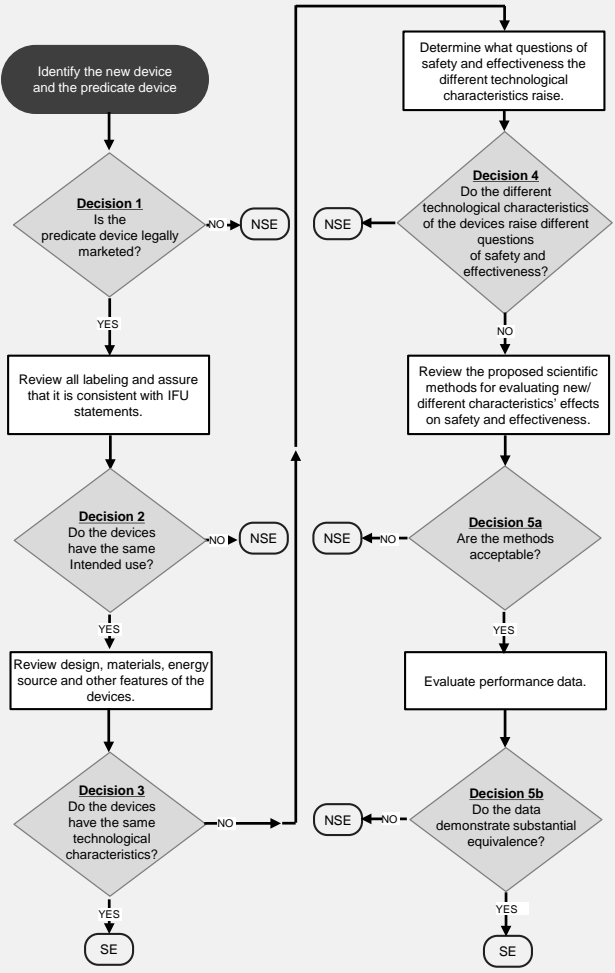
FDA guidance and recognized standards

Focus on Differences

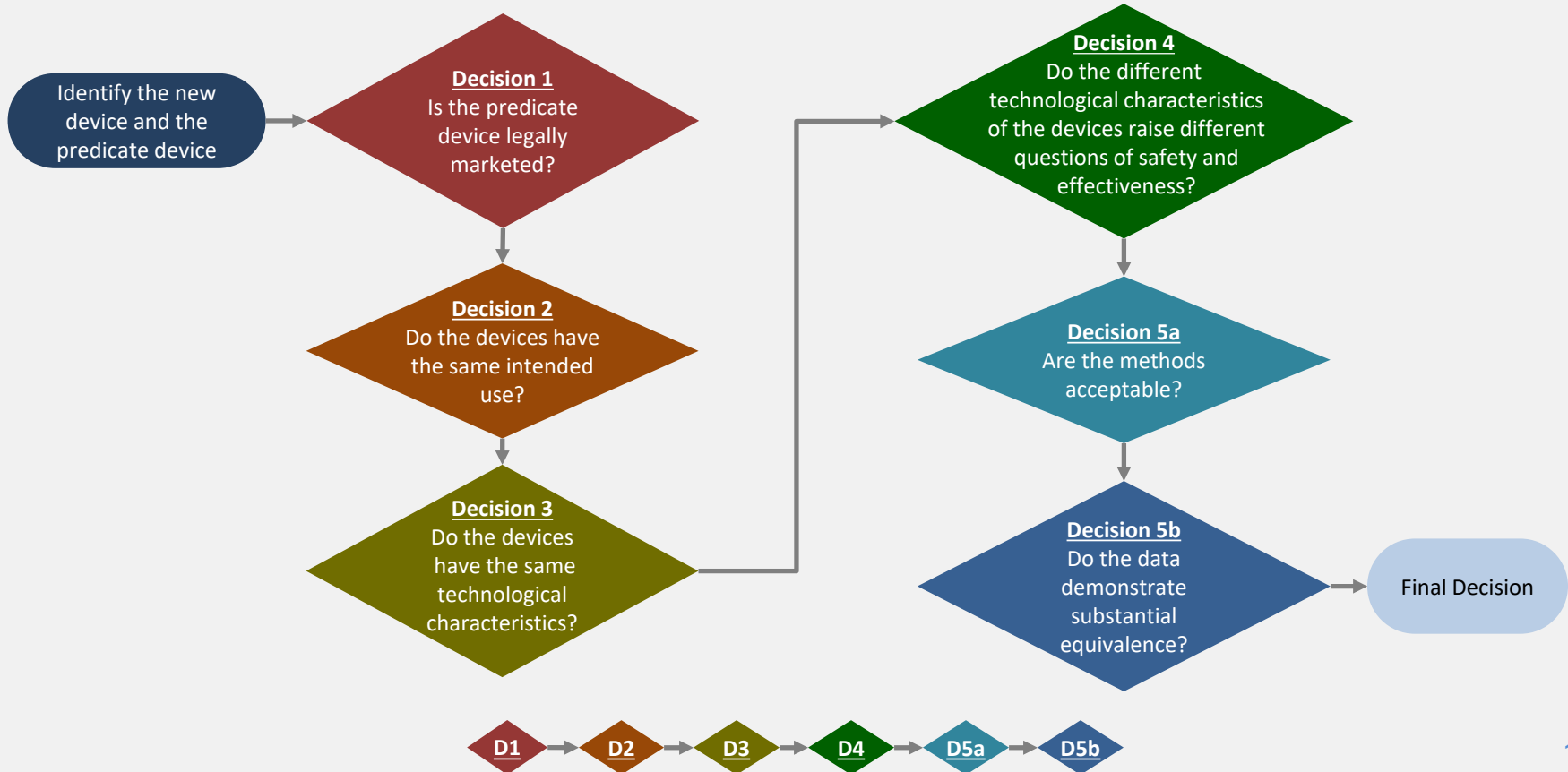
Between new and predicate device—
use 510(k) Decision Making Flowchart

[510\(k\) Decision-Making Flowchart](#) from [The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\]](#)

The “Evaluating Substantial Equivalence” Guidance Flowchart is Our Framework



Color-Coded Flowchart for Navigation



We Will Walk Through A Memo

I. Purpose and History

The 510(k) holder _____ would like to manufacture and distribute a new radiographic system into interstate commerce. The proposed class II device is a stationary x-ray system. The device is intended for general purpose radiographic procedures images. It is regulated under 21CFR §892.1680 with product code KPR. The identified predicate device is a stationary x-ray system from _____ (Kxxxxxx) with product code KPR.

The stationary radiographic system consists of a **tube rail stand, a floating table, a tube, a collimator, wireless detector, and generator.**

Main differences from the predicate include:

- Addition of wireless detectors (not cleared in any previous submission)
- Addition of post-processing options to a software package including virtual grid (other parts of software were cleared in the primary predicate submission). A key aspect of the review is the image quality improvement and dose reduction claims associated with the modified software's new postprocessing functions.

In terms of compatibility / integration, the wireless detectors and generator have the same technological specifications that were intended to be used with the software.

In response to the reviewer's request for more information, the sponsor provided additional information (xxxx) (____) and addressed all identified deficiencies. Following the final analysis of all submitted information, the subject device was found Substantial Equivalent (SESE) to the predicate device.

[TPLC Information](#) [Recall Information](#) [Histories/Alerts](#)

A search has been completed in the MAUDE and RES databases. There are no MAUDE reports or recalls related to the subject and predicate devices.

II. 510(k) Summary/Statement

510(k) Summary/Statement

Was a 510(k) Summary or Statement provided? Summary Statement

The content of the 510(k) Summary is ... [click common problems with 510k summary here](#)

Reviewer Recommendation

The 510(k) Summary/Statement is [not] acceptable.

III. Device/System Description

Is there a new intended use, or different technology that raises different questions of SAE? Yes No

Device Description Information Red = Inadequate or Unanswered Yellow = Marked

Device is life-supporting or sustaining: No

There are direct/indirect patient contacting components: Yes

• Device or a component is an implant: No

Before Using the Flowchart

<p>Where To Look</p>	<ul style="list-style-type: none"> ▪ CDRH Premarket Review Cover Sheet (Form FDA 3514) ▪ Cover letter ▪ 510(k) summary ▪ Substantial equivalence discussion
<p>What To Do</p>	<ul style="list-style-type: none"> ▪ Review purpose for 510(k) submission ▪ Ensure differences from predicate are clearly and consistently described ▪ Verify product codes and regulation numbers for proposed and predicate devices ▪ Look for previously-related submissions from sponsor: <ul style="list-style-type: none"> ▪ Check TPLC database for previous submissions for similar devices from sponsor (NSE, Q-Sub). ▪ Check predicate for recalls using Recalls database ▪ Check MAUDE database for medical device reports (MDRs) associated with device type
<p>What To Document</p>	<ul style="list-style-type: none"> ▪ Summary of purpose for the submission, including: <ul style="list-style-type: none"> ▪ Device product code and regulation number ▪ Differences from the predicate ▪ Explanation of how related submission (if available) affects review of submission ▪ Explanation of how MDRs and/or recalls (if available) affect review of submission

Use MAUDE for MDR Search

MAUDE - Manufacturer and User Facility Device Experience

[FDA Home](#) [Medical Devices](#) [Databases](#)

The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters ¹ (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

[Learn More](#)

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Search Database [Help](#) [Download Files](#)

Product Problem	<input type="text"/>	
Product Class	<input type="text"/>	
Event Type	Manufacturer	<input type="text"/>
Model Number	Report Number	<input type="text"/>
Brand Name	Product Code	<input type="text" value="KPR"/>
Date Report Received by FDA (mm/dd/yyyy)	<input type="text" value="07/01/2010"/> to <input type="text" value="07/31/2018"/>	

[Go to Simple Search](#) Records per Report Page [Clear Form](#)

Search Reminders

- Always enter the device product code
- Enter manufacturer names in part and full
- Spelling matters and avoid plurals

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM

Use Recalls Database

Medical Device Recalls

● FDA Home ● Medical Devices ● Databases

This database contains Medical Device Recalls classified since November 2002. Since January 2017, it may also include correction or removal actions initiated by a firm prior to review by the FDA. The status is updated if the FDA identifies a violation and classifies the action as a recall and again when the recall is terminated. FDA recall classification may occur after the firm recalling the medical device product conducts and communicates with its customers about the recall. Therefore, the recall information posting date ("create date") indicates the date FDA classified the recall, it does not necessarily mean that the recall is new. [CBER recall information is available here.](#) [More about Medical Device Recalls](#)

Search Database Help

Product Name Product Code In-Vitro Devices

Recall Class PMA/510(K) Number

Recall Date to Recall Number

Reason for Recall

Recalling Firm

Root Cause

Sort by

[Quick Search](#) [Clear Form](#)

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm

Search Reminders

- Always enter the device product code
- Always enter 510(k) number of predicate device
- Enter name of recalling firm in part and full

Before You Go Further!

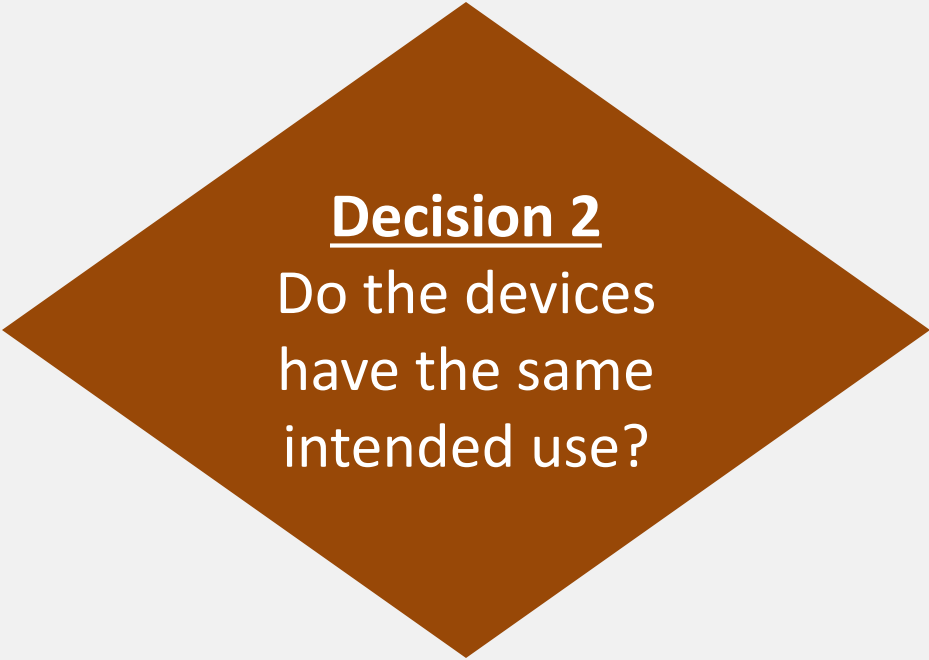
CADx or CADe

- Computer-Aided Diagnostic or Detection
- Not eligible for Third-Party Review
- Require clinical evaluation
- Remove feature from Third-Party Submission
- New device example – CADe under “Software” section

Decision 1

Is the predicate
device legally
marketed?





Look at Indications for Use (IFU)



Where To Look	<ul style="list-style-type: none">▪ Indications for Use Statement (Form FDA 3881)▪ Proposed labeling (510(k) summary, User manual, Brochures)
What To Do	<ul style="list-style-type: none">▪ Check consistency of IFU throughout submission▪ Review details of IFU, intended population and prescription/over-the-counter information▪ Review promotional material (including claims) in detail for any new indications.
What To Document	<p>If different indications for use than predicate:</p> <ul style="list-style-type: none">▪ Highlight differences and explain why they don't affect overall intended use <p>If no new indications for use:</p> <ul style="list-style-type: none">▪ Document that indications are same as predicate▪ Document that labeling is consistent with IFU.



Labeling Information

- Indications for use, Rx icon or prescription statement
- Quality Control manual
 - Description of standards, quality criteria, or limits of acceptance for each monitored parameter
- Image quality and dosimetry performance testing information
- Integration information:
 - other devices/components with which the device is compatible
- Review and evaluate all device specific claims



Labeling: Pediatric Information

- Description of special pediatric features
- Labeling information for pediatric use of X-ray imaging device
- Appropriate pediatric cautions/warnings and instructions for use
- This caution statement: “Use special care when imaging patients outside the typical adult size range”



Labeling: Pediatric Information

- Memo should document:
 - these findings
 - risk assessment on pediatric use
- Sample Summary
 - Appendix A of Pediatric Guidance
 - [Pediatric Information for X-ray Imaging Device Premarket Notifications](#)



IFU Section

Comparison of Indications for Use								
Subject								
510(k) #: Rx/OTC: Rx								
Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/Newborn
Yes	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unknown	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Indications for Use: The <device name> is a stationary/mobile x-ray system intended for use in general projection radiographic images of human anatomy for adults and pediatrics in all general-purpose diagnostic procedures, excluding mammographic applications.								
Predicate(s)								
Submission#: Rx/OTC: Rx								
Intended Population: Adults								
Indications for Use: <Device name> is a stationery X-ray system intended for obtaining radiographic images of various portions of the human body in a clinical environment.								
The <device name> is not intended for mammography, angiography, interventional, or fluoroscopy use.								

- IFU statements are similar, except that proposed device explicitly lists pediatrics in intended population.
- Although IFU wording is different, intended use for general radiography applications is the same.
- However, in the proposed labeling a CADe/CADx feature for fracture detection and pulmonary contusion diagnosis was discovered. This labeling is not consistent with the IFU, and changes the intended use of proposed device.

This is a deficiency.



Summary of Labeling

Labeling Information

Prescription statement included: Yes

Indications for Use consistent with IFU page: Yes

Appropriate Contraindications, Warnings, Precautions & Adverse Events: Yes

Instructions in accordance with guidance: Yes

Appropriate labeling inside device: Yes

Appropriate labeling outside device: Yes

Appropriate instructions for use labeling: Yes

In both the hardware and software documents, the sponsor provided the following information:

- Manufacturer's Contact Information
- Prescription Use Statement
- Intended Use / Indications for Use
- Relevant notes, cautions, warnings, and/or contraindications
- Symbols (with description)
- Device Descriptions
- Hardware Requirement (software)
- Accessories
- Directions for Use (check for radiation safety information)
- Description of quality assurance tests (and action limits)



Labeling Review

- Performance information for the flat-panel digital imagers, and the QC/maintenance information
- Sponsor did not follow FDA final guidance “Pediatric Information for X-ray Imaging Device Premarket Notifications”
 - **This is a deficiency.**



Review of Claims

- At equivalent image quality, the device results in 50% less dose to the patient.
- Reviewer Comment:
 - Sponsor provided simple Likert-type scoring of clinical images to support quantitative claim
 - Study did not include assessment of physical parameters.
 - Study is not accurate to support claim. A more carefully designed clinical study with a clearly established baseline and endpoints would be needed. For example ROC curves would be an acceptable analysis acceptance method. This is a deficiency.
- Conclusion: Claim is unacceptable.



Example Resolution

Example Deficiency:

In your proposed labeling section, you provided a quantitative dose reduction claim for your new device and you have provided a Likert-type study to support this. However at this time, the Agency finds the overall methodology of your data analysis, including the simple Likert scoring of clinical images to not support the quantitative claim. You have not established that the baseline dose (prior to application of the new post-processing feature) is optimized. As a result, both the higher dose and lower dose images may have been collected on a part of a dose response curve where the reader cannot distinguish between the images to within error. Therefore to establish that your new post-processing feature enables dose reduction by improving image quality, a more carefully designed reader study with predefined endpoints and a carefully established dose baseline is needed to support this claim; ROC is an example of an acceptable type of analysis method. We strongly suggest that you remove the claim and submit a pre-submission discussion to address data collection and analysis methods in a future 510(k). This information needs to be corrected to provide the end user with accurate device performance data.

Sponsor response in supplemental documentation:

We have removed the dose reduction claim from this submission.

This is adequate.

Review of Claims

- Image quality: “At equivalent dose, the device results in 41% improvement in image quality.”
- Reviewer comments:
 - No clear point of comparison for claim or basis explained in labeling
 - Claim based on noise reduction
 - only one measure associated with image quality
 - Observation of images by qualified radiologist cannot be quantified.
- Conclusion: This is unacceptable. Sponsor removed claim.



Review of Claims

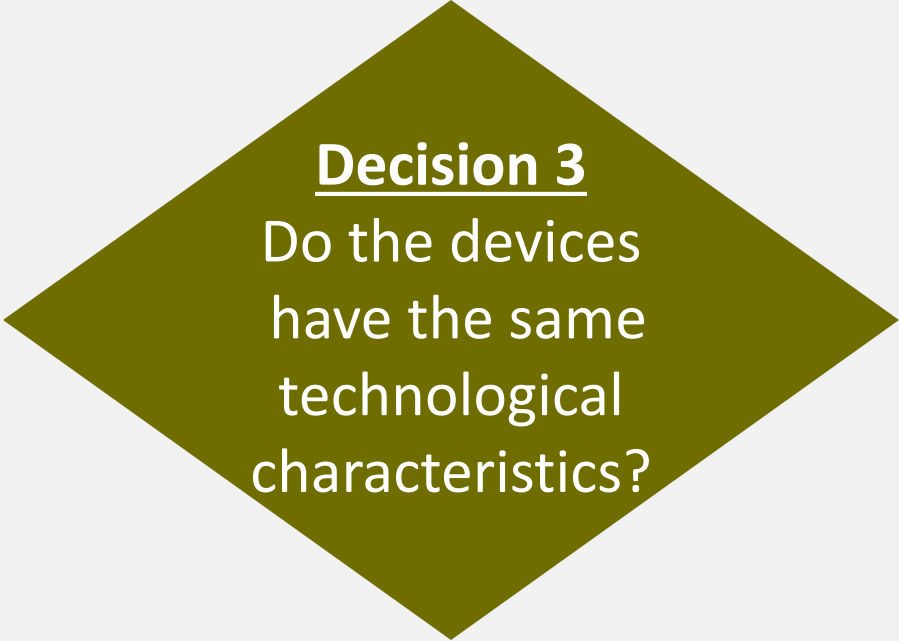
- Contrast: “AutoGrid is optional feature that improves visibility of diagnostic chest and abdomen x-ray images by decreasing scatter radiation when grid is not used in image acquisition.”
- Reviewer comments:
 - Claims are substantiated with a statement from a board-certified radiologist on an anthropomorphic phantom study . See performance testing section.
- Conclusion: Claim is acceptable.



Review of Claims

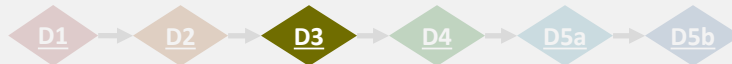
- Clinical: Superior detection of simple (non-displaced) fractures, displaced fractures, and pulmonary contusion detection in standard PA (posterior anterior) chest x-rays compared to conventional chest x-rays.
- Reviewer comments:
 - The claim is associated with the CAdE/CADx feature which is not supported by any data.
 - Deficiency issued to sponsor
- Conclusion: Claim is unacceptable, sponsor removed claim.





Describe Device and Compare Technology

Where To Look	<ul style="list-style-type: none">▪ Device description section▪ Substantial equivalence discussion▪ Software section
What To Do	<ul style="list-style-type: none">▪ Review all components of entire x-ray system.▪ Check to see whether components of x-ray system have been previously cleared.▪ Compare components with predicate device, especially:<ul style="list-style-type: none">▪ X-ray generator specifications▪ Detector type and specifications▪ Image acquisition and post processing software
What To Document	<ul style="list-style-type: none">▪ Summary description of x-ray system, indicating both hardware and software components▪ More detailed explanation of new/modified features, focusing on features different from predicate.▪ Accompanying 510(k) numbers for previously-cleared components



Summary Description of New Device

Device Description Information

Device uses software/firmware: Yes

- **Connection Types:** Cloud, Network, Wireless

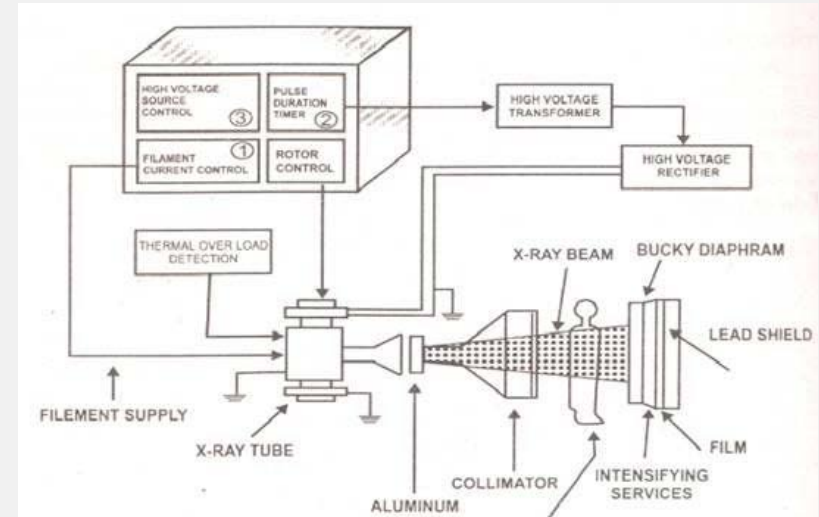
Device or component needs sterilization: No

Environments of Use: Professional Healthcare Facility

The Device/System is electrical: Yes, it is mains powered Only

- **Wireless Technology is used:** Yes

Radiographic x-ray system consisting of a tube rail stand, a bucky stand, and a floating table, a tube, a collimator, wireless digital detector, and a generator. Sponsor states that the device is a floor-mounted stand, table, and a wall stand.



Differences Between New and Predicate Devices

- Addition of wireless detectors (in new device)
- Addition of post-processing options to a software package (modified)
 - Key: image quality improvement and dose reduction claims associated with new post-processing functions.
 - Autogrid (new feature)
 - Low Dose Protocol (new feature)
- Different generator power options



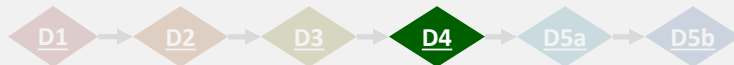
Common Occurrences and Best Practices

- Issue: Sponsor state that software is exactly the same as predicate device
 - Clarify with sponsor that software is has not changed to accommodate new hardware
- Issue: Hardware components are different from those of predicate
 - Focus on integration testing of hardware components with software



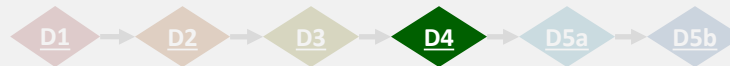
Decision 4

Do the different technological characteristics of the devices raise different questions of safety and effectiveness?



Focus on Differences in Technological Comparison

Where To Look	<ul style="list-style-type: none"> ▪ Device description section ▪ Substantial equivalence discussion ▪ Software section
What To Do	<ul style="list-style-type: none"> ▪ For each new / modified component of x-ray system compared to the predicate, assess whether there are new questions of safety and effectiveness
What To Document	<ul style="list-style-type: none"> ▪ Document questions raised by technological characteristics not applicable to predicate ▪ Explanation of why new / modified components do / do not raise any different questions of safety and effectiveness to the x-ray system



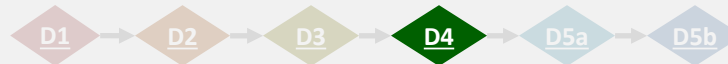
Characteristics	<u>New Device</u>	<u>Predicate Device</u>
X-ray Generator		
kV range	40-150 kV	40 – 125 kV
Milli ampere sec (mAs) range	0.1 – 320 mAs	0.1 – 320 mAs
Milliampere range	50 – 400 mA	50 – 320 mA

- X-ray generators have different kV and mA ranges resulting in different power ratings.
- Though increased, kV and mA ranges for the new device are within the appropriate ranges for imaging of the human anatomy.
- Does not raise new questions of safety and effectiveness.



Characteristic	<u>New Device</u>	<u>Predicate Device</u>
Detector		
Type	Digital wireless flat detector	Digital wired flat detector
Scintillator	gadolinium oxysulfide (GadOx - Gd ₂ O ₂ S)	Cesium Iodide (CsI)
Detector size	15" x 18"	15" x 18"
Active area	14.6" x 17.6"	14.3" x 17.3"
Pixel size	136 μm	148 μm
MTF @ 50%	2.5 lp/mm	3.0 lp/mm
DQE	1.0 mm ⁻¹ = 20% 2.0 mm ⁻¹ = 10%	1.0 mm ⁻¹ = 26% 2.0 mm ⁻¹ = 12%

- New device uses a wireless detector with GadOx as scintillating material; predicate device uses a wired detector with CsI
- New device detector has worse DQE and MTF performance, likely due to scintillator material.
- Sponsor is asked to provide a reference device with equivalent/worse performance to predicate.
- Differences in connectivity of detectors to x-ray system can result in integration issues
 - Does not introduce different questions of safety/effectiveness.



Characteristic	<u>New Device</u>	<u>Predicate Device</u>
Software platform		
Software	Ready Image v1.1	Ready Image v1.0
<i>Features</i>	<i>AutoGrid</i>	Not present
	<i>LDP</i>	Not present

- Additional features added to the already-cleared software may influence diagnostic quality of produced images from system

AutoGrid

- AutoGrid software option is to enhance image contrast in general radiographic images of chest and abdomen images by reducing the effects of scattered radiation on the image, post-acquisition.
- New feature is not intended to replace any physical grid.
- Questions of safety/effectiveness are same for any x-ray system e.g. image quality at a reasonable dose.

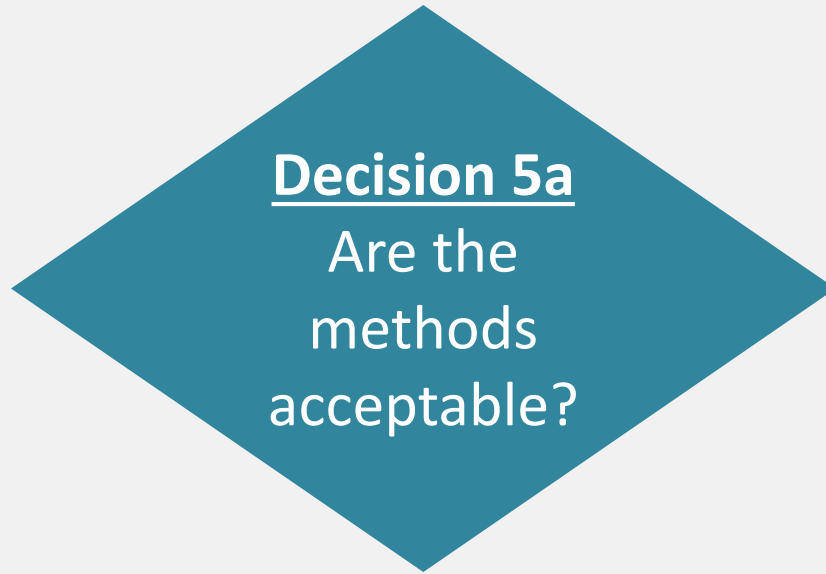


Characteristic	New Device	Predicate Device
Software platform		
Software	Ready Image v1.1	Ready Image v1.0
<i>Features</i>	<i>AutoGrid</i>	Not present
	<i>LDP</i>	Not present

LDP

- LDP feature enhances image quality by using advanced noise reduction algorithm.
- Feature is intended to be used together with lower dose protocols , to allow low dose images with same diagnostic quality as images taken at full dose.
- Feature does not introduce new questions of safety/effectiveness.





Review Methods of Performance Testing

<p>Where To Look</p>	<ul style="list-style-type: none"> ▪ EMC, electrical, mechanical, thermal and radiation safety - often covered by standards conformance ▪ Sterilization and shelf life ▪ Biocompatibility ▪ Software – verification and validation testing ▪ Performance testing – bench, clinical
<p>What To Do</p>	<ul style="list-style-type: none"> ▪ Focus on performance testing for new / modified components, especially: <ul style="list-style-type: none"> ▪ Detectors – <ul style="list-style-type: none"> ▪ MTF, DQE, NPS and other recommendations in SSXI guidance ▪ FDA wireless guidance ▪ Post processing software ▪ For claims, make sure the sponsor provides performance testing to substantiate claims. ▪ Did the sponsor appropriately support their testing methodology with reference to appropriate FDA guidance, reference devices or secondary predicates, standards or literature ▪ <i>Note: Please contact FDA immediately upon discovery of quantitative dose & image quality improvement claims and clinical performance claims</i>
<p>What To Document</p>	<ul style="list-style-type: none"> ▪ Each performance test provided and corresponding evaluated new / different characteristics ▪ Conclusion on whether all concerns on safety/effectiveness are adequately addressed by supplied performance testing.



Look at 5 Types of Performance Testing

- Software
- Electrical Safety, Electromagnetic Compatibility (EMC) and Radiation Safety
- Cleaning, Disinfection and Sterilization
- Biocompatibility
- Nonclinical and Clinical Performance Testing



Look at 5 Types of Performance Testing



Software

States device is Moderate
Level of Concern



Electrical Safety, EMC, and Radiation Safety



Cleaning, Disinfection and Sterilization



Biocompatibility



Nonclinical and Clinical Performance Testing

References

- [Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices](#)
- [General Principles of Software Validation; Final Guidance for Industry and FDA Staff](#)
- [Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices](#)



Software

- Level of Concern: **moderate**
- Documentation based on **moderate** level of concern
 - [Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices](#)
- Clarify and document whether software is actually changing
 - If no new features, but new hardware components:
 - focus on integration issues in V&V
 - Modifications to existing software platforms- risk analysis and corresponding verification and validation
 - If new: pick features that have lot of interaction with other software or hardware (e.g., AEC) and trace through SRS, SDS, V&V and risks
- Ensure and document validation of final, finished device



Software Documentation

Sponsor provided full software documentation according to a **moderate** level of concern.

Because the software is a modification of an existing FDA-cleared device, the review focused on

- Risks analysis and corresponding V&V of new software features
- Integration of new hardware components with software

Example of hazard for Auto Grid feature and verification/validation testing:

Hazard – AAD-78 <i>Autogrid not applied to post acquisition images</i>	<ul style="list-style-type: none"> • Potential Hazard/ Failure – Misdiagnosis • Potential Cause of Hazard/ Failure - Wrong Post Image • Potential Effect of Hazard/ Failure – Misdiagnosis / Examination delay / Re-exposure
Mitigations – 3.19-AAD	<ul style="list-style-type: none"> • Prompt user for Autogrid option On/Off prior to acquisition sequence • User manual instructions on how to use Autogrid feature correctly.
Verification – VDS.3.19.AAD	<ul style="list-style-type: none"> • Operate Autogrid only when ON AutoGrid option - PASSED • The functional operation AutoGrid smoothly on / off - PASSED • After setting the option On AutoGrid it should proceed smoothly perform Post-processing - PASSED • AutoGrid images should be obtained within 10 seconds after image acquisition – PASSED



Cyber Security

Risk Management	<p>Adequate Threat Model?: Yes</p> <p>Cybersecurity Vulnerabilities/Risks: Data is received via Wifi, LAN. There is a risk of the unauthorized access to data in the system. Such risk lead to patient privacy issues, and may be a threat to patient health and life. In addition, there is a USB port located on the workstation that may be susceptible to unauthorized access.</p> <p>Cybersecurity Controls: The system requires user authentication to grant access to trusted users, automatic time out, and activity logging. The user manual also recommends the use of the anti-virus SW to protect the system.</p> <p>Adequate Risk Management?: Yes</p> <p>Adequate Traceability?: Yes</p>
Plan for Continuing Support	<p>Upgrade Plan: As defects are reported, they are managed according to the Defect Management Process. The software maintenance stream runs for two weeks between software update releases and is focused on fixing defects or adding targeted integration points.</p> <p>Sufficient Upgrade Plan?: Yes</p>
Plan for Malware - Free Shipping	<p>Shipping Plan: Approved software updates are allowed to be installed by authorized field service engineers. This is the only way to install new software onto the system. The software update and installation mechanisms are not exposed and are not available to unauthenticated users</p> <p>Sufficient Shipping Plan?: Yes</p>
Labeling	<p>Labeling: The user manual recommends the use of the anti virus SW, Manual Workflows, Back-up Systems and other risk mitigation measures and states that they are the responsibility of the customer to implement and manage for the protection of the system.</p> <p>Sufficient Labeling?: Yes</p>
Interoperability	<p>Number of Electronic Interfaces (EI): 1 USB</p> <p>Electronic Interface is inactive?: No</p> <p>Electronic Interface is only meant for service?: Yes</p>



Look at 5 Types of Performance Testing



Software



Electrical Safety, EMC, and Radiation Safety

States device conforms
with IEC 60601-2-54



Cleaning, Disinfection and Sterilization



Biocompatibility



Nonclinical and Clinical Performance Testing

See FDA form 3654 to
ensure all standards used
in the submission are listed



Electrical Safety, EMC, and Radiation Safety

- Ensure testing has been performed on final finished device
- Document that the sponsor has conformed to the FDA recognized version of the standards

Example of Documenting Conformance

Conformance to particular standard (IEC 60601-2-54) sufficiently addresses system safety, as this standard incorporates base safety standard (IEC 60601-1) and a number of collateral and reference standards that cover EMC (e.g., IEC 60601-1-2), electrical, mechanical, thermal, and radiation safety.



Look at 5 Types of Performance Testing

- Software
- Electrical Safety, EMC, and Radiation Safety
- Cleaning, Disinfection and Sterilization**
- Biocompatibility
- Nonclinical and Clinical Performance Testing

Sponsor should provide appropriate cleaning instructions

Reference

[Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling](#)



Cleaning, Disinfection, Sterilization

- **Ensure the sponsor provided appropriate cleaning instructions**
 - Recommendation of a cleaning agent

Reprocessing, Sterilization and Shelf-Life

The device is non-sterile when used, and user manual includes cleaning instructions.

Reviewer Recommendation

Cleaning, Sterilization, Shelf-Life and Reuse descriptions are acceptable.



Look at 5 Types of Performance Testing

- Software
- Electrical Safety, EMC and Radiation Safety
- Cleaning, Disinfection & Sterilization
- Biocompatibility**
- Nonclinical and Clinical Performance Testing

Usually not applicable to
X-ray systems

Reference [Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing](#)



Biocompatibility

- Ensure there are no patient contacting components
- State whether manual recommends use of “exam paper” or any separating material between patient and system components

Biocompatibility

The sponsor proposes the use of a barrier (e.g., sheath or drape). As a result, there are no patient-contacting components.

Reviewer Recommendation

The Biocompatibility information is acceptable.



Look at 5 Types of Performance Testing



Software



Electrical Safety, EMC, and Radiation Safety



Cleaning, Disinfection and Sterilization



Biocompatibility



Nonclinical and Clinical Performance Testing

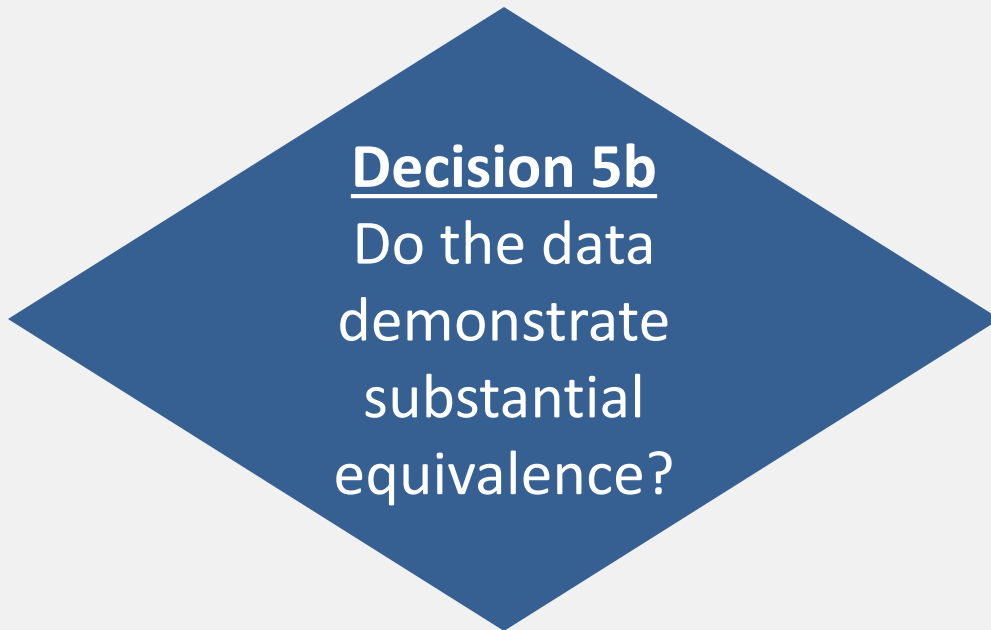
Determine what testing is necessary based on predicate & new/modified features

Questions to answer

- Are there standards or well-accepted test methods?
- What performance testing methods were used for predicate and secondary/reference devices?
- Are these methods appropriate for the new device?
- For different features, are there any additional tests needed for the new device?

Reference [Guidance for the Submission of 510\(k\)s for Solid State X-ray Imaging Devices](#)





Flow Chart: Decision Points 5b

<p>Where To Look</p>	<ul style="list-style-type: none"> ▪ EMC compatibility and electrical safety ▪ Sterilization and shelf life ▪ Biocompatibility ▪ Software – V&V testing ▪ Performance testing – bench, clinical
<p>What To Do</p>	<ul style="list-style-type: none"> ▪ Identify all risk analysis methods used to assess impact of new / modified features. ▪ Based on risk analysis, summarize all V&V activities required including test and acceptance criteria applied ▪ Focus and highlight testing and results for new / modified features e.g. software features that impact output image
<p>What To Document</p>	<ul style="list-style-type: none"> ▪ Description of V&V activities and conclusion ▪ Brief description of bench testing (clinical if applicable) and discussion on how the results demonstrate substantial equivalence.



Bench Testing

- Sponsor provided testing evaluating the system for its signal linearity, quantum-noise-limited range of operation, lag, spatial resolution in terms of the modulation transfer function (MTF), image noise in terms of the Wiener noise power spectrum (NPS), and dose efficiency in terms of the detective quantum efficiency (DQE) according to the “Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices”.
- Sponsor stated that the measurements were made in accordance with IEC 62220-1, which describes a standardized method by which the MTF, NPS and DQE can be measured.
- Provided documentation per Wireless Guidance



Bench Testing

MTF

- MTF curves provided in both -x and -y directions for the new and predicate devices.
- For the evaluated acquisition parameter, the new device's detector had a lower MTF in both -x and -y directions indicative of lower spatial resolution than the predicate device.
- May be attributed to the difference in scintillator material.
- Does not demonstrate that the new device's performance is as effective as the predicate, and is not acceptable.

This is a deficiency



Bench Testing

DQE

- DQE for both new and predicate devices are shown in Figure 4.5 and the integrated DQEs, δ , are listed in Table 4.5 of Section 18. At 10 keV, the new device's detector has both the highest resolution and largest area, although the predicate's CsI has a slightly higher DQE at low frequencies.
- At higher energies, new device's Gadox-based scintillator rapidly deteriorates due the reduced absorption, and the predicate's CsI-based scintillators gets better.
- Predicate detector's CsI detector has higher absorption efficiency, making it better when looking at the integrated DQE.
- Does not demonstrate substantial equivalence between the new and predicate devices.

This is a deficiency.



Bench Testing

AutoGrid Phantom Image Evaluation

- Sponsor provided anthropomorphic phantom study for the AutoGrid (scatter correction) software feature.
- Includes range of anatomical regions and patient size (chest AP and abdomen supine for medium, large, extra-large and child patient size, with the PBU-60 Phantom).
- Board certified radiologist evaluated the images.
- Considered adequate for this software modification because there were no quantitative claims and no claims that the feature could be used to replace use of a real grid.

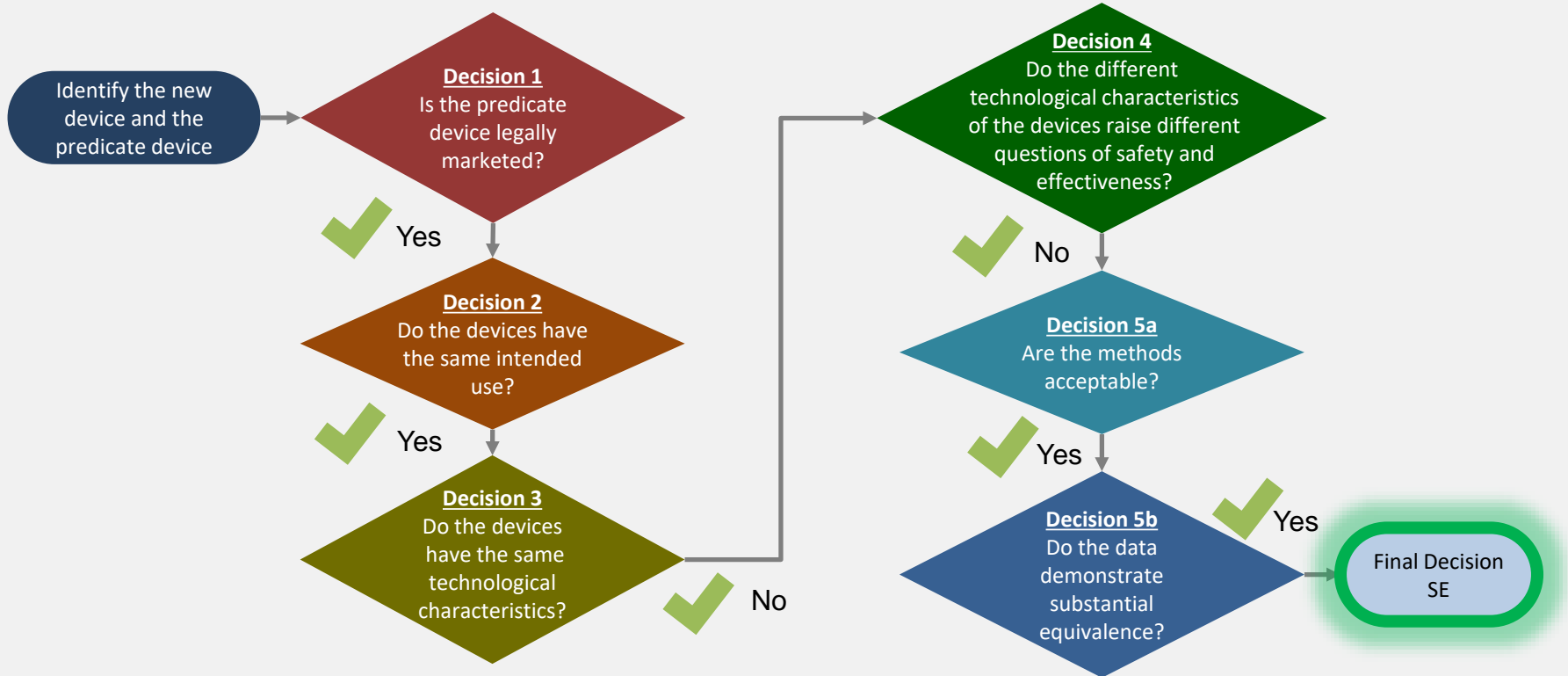
LDP

- Sponsor provided a clinical image evaluation report
- Includes comparison of 30 chests images (PA & Lateral) with and without LDP
- Statement from a board-certified radiologist (CV attached in Attachment).
- Considered adequate for this software modification an associated quantitative 50% dose reduction claim.



Substantial Equivalence Determination	Yes	No
1. Is the predicate device legally marketed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Do the devices have the same intended use?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Please explain how the intended use of the new device is similar to or different from the predicate device: Both devices are intended for general projection radiographic images of human anatomy in all general-purpose diagnostic procedures.		
3. Do the devices have the same technological characteristics?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Please describe the different technological characteristics: The new device utilizes a wireless digital detector with Gadox as scintillator material compared to the predicate's wired CsI digital detector. In addition, the new device has a modified version of the existing image software used in the predicate. These features include AutoGrid (virtual grid) to reduce x-ray scatter, and LDP (low dose protocol) to reduce patient dose up to 50% by noise reduction.		
4. Do the different technological characteristics of the devices raise different questions of safety and effectiveness?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5a. Are the methods acceptable?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5b. Do the data demonstrate equivalence and support the Indications for Use?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Please explain how the data do or do not demonstrate substantial equivalence: The new device conforms to IEC 60601-2-54, which covers most safety related concerns. Sponsor provided adequate data according to SSXI, wireless, pediatric, cybersecurity and software guidances. Sponsor supported MTF and DQE performance through comparison to a reference device. AutoGrid and LDP features were further supported through an anthropomorphic phantom study reviewed by a board-certified radiologist. Sponsor removed quantitative image-quality improvement and dose reduction claims associated with these features.		

Substantially Equivalent



510(k) Summary

- Ensure all administrative information is correct:
 - 510(k) numbers, trade/proprietary names, classification name, regulation number, product code
- Performance data section described
- Information in 510(k) should reflect the cleared device

Revisiting Keys to Success

- Thoroughly identify and compare existing and new/modified components of new device to predicate
- Use the 510(k) Decision-Making Flowchart
- Be familiar and use relevant resources and references

Acronyms

- TPLC – Total Product Life Cycle
- MDR – Medical Device Reporting
- MAUDE – Manufacturer and User Facility Device Experience
- NSE – Not Substantially Equivalent
- QSUB – Q-Submission
- Rx - Prescription
- OTC – Over the counter
- MTF – Modulation Transfer Function
- NPS – Noise Power Spectrum
- DQE – Detector Quantum Efficiency
- CADe – Computer Aided Detection

Resources

- [The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\]](#)
- IEC 60601-2-54 Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- IEC 62220-1-1 Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1-1: Determination of the detective quantum efficiency - Detectors used in radiographic imaging
- [Guidance for the Submission of 510\(k\)s for Solid State X-ray Imaging Devices](#)
- [MAUDE – Manufacturer and User Facility Device Experience](#)
- [Medical Device Recall Database](#)
- [21 CFR 892.1680 - Stationary x-ray system](#)
- [21 CFR 892. 1720 - Mobile x-ray system](#)
- [Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices](#)
- [Content of Premarket Submissions for Management of Cybersecurity in Medical Devices](#)
- [Pediatric Information for X-ray Imaging Device Premarket Notifications](#)
- [Radio Frequency Wireless Technology in Medical Devices](#)
- [Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification \[510\(k\)\] Submissions](#)



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