Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices

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Guidance for Industry and Food and Drug Administration Staff

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

Office of In Vitro Diagnostics and Radiological Health (OIR)
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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-1997-N-0389. This guidance was originally assigned the docket number 97N-0390. The docket number was changed to FDA-1997-N-0389 as a result of FDA's transition to its new docketing system (regulations.gov) in January 2008. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 644 to identify the guidance you are requesting.

GUIDANCE[1] FOR THE SUBMISSION OF 510(K)S FOR SOLID STATE X-RAY IMAGING DEVICES

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[1]This document is intended to provide guidance. It represents the Agency's current thinking on SSXI's. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

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II Scope

This guidance applies to the category of medical imaging devices, Solid State X-ray Imagers (SSXI), that convert x-ray patterns into electrical signals. The signals can in turn, with or without processing, be converted into visible images for use in medical diagnosis. These devices are intended to be used in place of conventional x-ray film/screen systems, and image intensifier based fluoroscopic and image recording systems. SSXI's indicated for mammography do not fall within the scope of this guidance.

III Purpose

As solid state device technology continues to progress, solid state x-ray imaging devices will assume an ever-increasing role in medical x-ray systems. This evolution will result in a significant number of premarket (510(k)) submissions for devices that utilize various forms of this technology. This document is intended to provide guidance on the type of data needed by the Center for Devices and Radiological Health (CDRH) to establish the substantial equivalence of an SSXI to a previously cleared conventional radiographic film/screen system, fluoroscopic image intensified imaging system, SSXI or similar device.

IV Description

The devices covered by this guidance are solid state transducers (typically flat rectangular panels) that intercept x-ray photons, and through one of several processes convert the photon energy into an electrical signal that is subsequently used to create a visible image. Some of the basic types currently available to perform the x-ray conversion are:

A. Scintillator - photodetector devices. A scintillator such as cesium iodide absorbs the input x-ray photons. The scintillator in turn emits visible spectrum photons that illuminate an array of photodetectors that create an electrical charge representation of the x-ray input. A matrix scan of the array converts the integrated charges into a modulated electrical signal.

B. Direct conversion devices. The input x-ray photons are absorbed in an x-ray sensitive material (e.g. photoconductor) that creates an electrical charge representation of the x-ray input. The charge is read-out by a matrix scan of the array (e.g. through switching transistors) that converts the charges into a modulated electrical signal.

C. Optically coupled CCD. A scintillator such as cesium iodide absorbs the input x-ray photons. The scintillator in turn emits visible spectrum photons that are optically coupled (via lens(es) or fiber- optics) to one or more charged coupled detectors (CCD). The CCD in turn converts the visible image into an electrical signal in the same manner as in a TV camera.

D. Photostimulable phosphor. The input x-ray photons are absorbed by a phosphor plate such as barium-fluoro-bromo-iodide creating trapped electrons just below the conduction band. Subsequent scanning of the plate with red or near-infrared laser light releases the electrons, a process that results in the emission of green, blue or UV light in proportion to the input x-ray exposure. The light is collected by a photomultiplier that converts it into a modulated electrical signal.

After the electrical signal is generated it is converted to a digital value and often processed to enhance the visibility of the viewed image. The resultant output signal can be transmitted to remote viewing sites, and/or it can be stored electronically for later viewing. The signals can also be input to a hard- copy device (e.g. laser scanner) to make paper or film copies of the images.

V Regulatory Requirements

Prior to marketing, new x-ray imaging devices must conform to the Radiation Control for Health and Safety Act of 1968 (RCHSA) and the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act of 1976.

Under RCHSA the devices must conform to the Performance Standards for Ionizing Radiation Emitting Products. Specifically they must meet applicable sections of 21CFR1020.30 Diagnostic x-ray systems and their major components, 1020.31 Radiographic equipment, or 1020.32 Fluoroscopic equipment.

Under MDA, a device may be cleared for marketing via a 510(k) premarket notification. To do so, the device must be shown to be substantially equivalent to a legally marketed predicate device. Predicate devices for SSXI's are preamendment or cleared devices that have the same or similar intended use(s) as the device being submitted for clearance. The fact that such a predicate may itself be exempt from
510(k) requirements does not exempt the SSXI's from this requirement (ref. 21 CFR 892.9 (b)). SSXI's operate using a different fundamental scientific technology than film or image intensifiers and, therefore, are not exempt from the requirements of 510(k).

Product Code "90 MQB" has been established for SSXI's and they are currently classified in Class II.

VI Nonclinical Considerations

In addition to the General Information required for all medical devices submitted for 510(k)

clearance (Ref.: 21 CFR 807.87) the following nonclinical information specific to SSXI's should also be included. This information will assist in determining the equivalence to the predicate device(s) identified by the sponsor.

Unless stated otherwise herein or by the manufacturer, all characteristics and measurements reported are assumed to be taken while the device is functioning at room temperature. For quantitative measurements that are reported, the degree of uncertainty should be included (e.g. error bars).

A. Physical Characteristics

1. Provide the overall dimensions including length, width, thickness and any shape characteristics that are unique to the device.

2. Provide the sensor element dimensions and spacings including the fill factor, the fraction of the exposed area of the device that is sensitive to incident x-rays. Also describe any features added to compensate for input photon loss resulting from inactive interelement spacing. Include total horizontal and vertical element count if applicable.

3. Provide the structure cross section showing schematically the elements of the device so that its means of x-ray conversion and signal generation are explained.

4. Describe the interconnections of the elements, and any active or passive elements that are used to store, switch or otherwise process the electrical signals in the detector itself.

5. Provide a schematic diagram of the elemental signal storage scheme and the overall "scanning" and readout mechanism. This may be included as part of "A.3." above.

6. Provide the input electrical power requirements with tolerance limits and effects of power noise on the operation of the device.

B. Operational Functions

1. Provide the method(s) of exposure, and for fluoroscopy, rates of response (frames per second). Describe a typical exposure sequence from turn-on of the device to presentation of the image to the user.

2. Provide the x-ray absorber(s), material description. Describe the primary x-ray detection material and its x-ray detection properties as a function of photon energy (keV) or wavelength (mm); including any nonlinear response characteristics.

3. Provide a description of the energy conversion mechanisms utilized (e.g. x-ray to

light to electrical signal). Describe all the processes in the device that involve energy conversion (e.g. x-ray to visible).

4. Describe the readout mechanisms, and techniques used to commutate detector elements. Describe the means used to sequentially read-out the signal from successive elements. Include maximum and minimum rates, and for fluoroscopic devices the means provided for establishing synchronization with display or recording devices.

5. Provide a description of the output data, and any direct access to output signals. Indicate what communications standard (e.g. DICOM) is used to format the data for downloading and analysis.

C. Functional Characteristics

1. For fluoroscopic devices, provide the output format of the video signal, sample waveform and standards applied. Provide a sketch or photograph of horizontal scan line and vertical field signals noting the key elements of signal.

2. Provide an estimate of Detective Quantum Efficiency (DQE) at low spatial and temporal frequency. Describe the method used to make the estimate, and the level of uncertainty due to propagation of error.

3. For quantum limited performance [i.e. The noise added by the SSXI does not exceed the x- ray quantum noise when operated in the normal range of exposures or frame rates.] provide data showing that the device operates in a quantum limited mode at the frame rates or exposure levels specified for its use. If not quantum limited, provide the range of exposures (for fluoroscopy: frame rates) where quantum limited operation is not achieved. *It is expected that all predicate devices exhibit quantum limited behavior over their normal operating ranges.*

4. Provide a plot of the modulation or contrast transfer function of the device. Indicate the device settings and input dose level required to obtain the measurement. If the transfer characteristic varies with any other function indicate how and provide the maximum and minimum transfer functions that the device provides when used with typical clinical exposures.

5. Quantify the effects aliasing has on the DQE and Modulation Transfer Function (MTF) of the device. If aliasing is evidenced from the pre-sampled MTF, quantitatively describe how it affects the resulting image. If there are no aliasing effects from the device explain why.

6. Provide a plot of the output signal level as a function of input dose level for a specified x-ray spectrum. The spectrum may be defined in terms of kVp and beam filtration. Plot so that any nonlinearities are clearly shown. Other methods of

showing the dynamic range capabilities of the device may also be used.

7. Lag or residual signal level from prior exposures, short term and long term: Describe, quantitatively where possible, any device characteristics (often due to electron or hole trapping) that cause the device to include in the output, signal components attributable to one or more prior exposures. Indicate the relative amplitude and decay characteristics of such signals.

8. Means provided to expose and/or readout subsections (partial areas) of the full SSXI: Describe, if this is a characteristic of the device, how it can be under-scanned so that only a portion of the total detector matrix is utilized.

9. Describe how x-ray beam alignment and collimation to the "active" area of the device will be achieved to meet the requirements of 21CFR1020.31 or .32. What signal(s) will the device provide to indicate the size and position of the active area? If no "under-scanning" capability is provided, so indicate.

10. Describe the allowable types and quantity of defects, and any methods of compensation or blanking that are utilized to compensate for allowable maximum output, minimum output or otherwise inoperative pixel elements.

11. Provide data or a plot of any change in detection sensitivity as a function of time after the device is "ready" (e.g. biased, erased, etc.) for the next exposure. Also indicate any other changes such as reduction in dynamic range that take place after the device is "ready."

12. Provide a plot of the latent image decay characteristic as a function of time and temperature. Also describe any impact on signal retention as a function of the number of erasures and/or exposures the device has experienced.

13. Recovery Time for radiographic devices: Indicate the time after readout is complete (including any preparation function) until the device is able to accept the next exposure.

D. Exposure Characteristics

1. Dose Requirements and reciprocity changes: Provide quantitative measurements of the input dose required to generate an image or video frame equivalent to that provided by a predicate device. Also indicate any changes in this characteristic that will occur with time and/or cumulative radiation exposure.

2. Stability of device characteristics with time (total integrated exposure): In addition to exposure requirement changes, indicate any other characteristics of the device that change with time and/or total integrated exposure.

3. Uniformity of device characteristics (large and small area): Describe any nonuniformity characteristics of the device that may cause large or small area changes such as shading.

4. Frame-Rate for fluoroscopic devices: Indicate the maximum number of images that can be generated per unit time and any characteristics that change as a function of frame rate. For any characteristics that do change, indicate how they change. If the frame rate limit is a function of another characteristic(s) [outside the SSXI] indicate which one(s) and indicate how that characteristic(s) impacts the frame rate.

5. Reuse Rate for radiographic devices: Indicate the maximum number of images that can be generated per unit time. If limited by other than the device itself, describe.

E. Safety Features

1. Indicate what means [e.g. ready signal] that are provided to indicate the SSXI is prepared to accept and process an x-ray input.

F. Test Results

1. Provide samples of test pattern images (SSXI and predicate) that show the ability of the device to provide images equivalent to those of a predicate device(s). Each image should have with it the x-ray factors used and the set-up parameters of the device. The test patterns must be clearly identified and all characteristics indicated (e.g. lp/mm for each bar group). The geometry of the test set-up must be indicated as well as the focal spot size of the x-ray source. The images may be on film recorded from the output, or VHS videotape in the case of fluoroscopy devices. Any signal processing used should be described.

2. Provide sample measurements of the characteristics described in C and D above; include the tolerance or level of uncertainty associated with each measurement.

VII Clinical Considerations

Nonclinical information may be sufficient to support the substantial equivalence of a subject to a predicate device for many types of modifications without the need to provide additional clinical data. For example, clinical information may not be necessary for the following types of modifications:

1. Overall change in the dimensions of the image receptor with otherwise identical materials
2. Change in the pixel size and resolution with the same x-ray detection material
3. Change in the image receptor's wireless functionality

Manufacturers may contact FDA and consider a pre-submission to seek feedback on whether clinical images may be necessary based on the results of the bench testing or type of modifications.

In addition to the nonclinical information described above, one of the following two options for providing clinical information should also be included if the nonclinical information alone would not be sufficient. Investigations involving clinical subjects must comply with 21 CFR Parts 50 and 56.

A. Concurrence study

1. Conduct and report the results of a concurrence study of 30 or more clinical image pairs (from the same or equivalent patients) that show the ability of the device to provide images of equivalent diagnostic capability to those of a cleared predicate device(s). For fluoroscopic devices, the study may be done "live" (as viewed by the user/evaluator) or from sequences on VHS videotape or film produced from the video signal. Each image should be supported by the x-ray factors and set-up used as well as the operating parameters of the device and any signal processing performed.

2. Sample images: Representative pairs of sample images (from those taken for VII.A. above) should be submitted for each anatomical region (and/or study) that is indicated for the device.

3. Other findings: Provide any other clinically significant findings that are discovered in the process of using the device.

B. Qualified Expert Evaluation

1. Clinical images from only the subject device may be submitted if they are accompanied by an evaluation of the images by a qualified expert. For purposes of this guidance:

   a. A qualified expert is a U.S. board certified (or equivalent) radiologist or a U.S. board certified (or equivalent) subspecialty physician or dentist experienced in imaging related to the device's intended use. We recommend that the physician have at least five years of experience following residency and fellowship. Fellowship training in the device-targeted clinical area is desirable. We recognize, however, that a relevant fellowship may not always exist. We also recommend that at least 50% of the reader's practice should be in the modality or sub-specialty related to the device's intended use.

   b. For non-US board-certified clinicians, equivalence to US board certification is assumed if the reading clinician graduated from a training program accredited by the Accreditation Council for Graduate Medical Education International (ACGME-I), or from programs approved by the American Board of Radiology (ABR) International Medical Graduate Alternate Pathway or by the Educational Commission for Foreign Medical Graduates (ECFMG). Board equivalence will be assessed by the FDA on a case-by-case basis.

2. The purpose of this evaluation is to determine if the radiographic images are of acceptable quality for clinical use by a qualified expert. The set of images should be representative of the range of clinical procedures and anatomical regions identified by the device's intended use. A full set of 30 images may not be necessary if the set of images can sufficiently demonstrate the range of capability of the system for the intended anatomical region(s).

   For example, for general purpose radiographic indications, FDA recommends evaluating one clinical image for the following anatomical regions (and/or studies):

   a. Chest LAT
   b. Chest PA
   c. Pelvic
   d. Abdomen
   e. C-Spine AP, lateral, odontoid view. Obliques may be included.
   f. L-Spine, AP and lateral
   g. Shoulder, AP, internal and external rotation
   h. Extremities (hand, wrist, elbow, foot, ankle, knee, etc.) AP, lateral, oblique or a complete series.

3. The qualified expert should evaluate the images for each case and provide an overall assessment of whether these image sets collectively are clinically adequate.

4. Any issue with image evaluation or image quality should be fully explained.

5. Each clinical image should be accompanied by its acquisition parameters, including x-ray exposure conditions (anode, filter, kVp, mAs, exposure, half-value layer), and estimated dose (e.g. dose-area product).

6. These clinical images should be included in the submission in pdf and DICOM format.

If the nonclinical information or clinical image evaluation raise any specific concerns regarding the device and its predicate, you should contact the Division of Radiological Health, Office of In Vitro Diagnostics and Radiological Health (OIR), to discuss the necessity and content of clinical data prior to submitting your 510(k).

VIII Labeling

A premarket submission for an SSXI device should contain information on device labeling. The information provided should include:

A. Indication(s) for Use: A general description of the disease(s) or condition(s) that the device will be used to help diagnose and the patient population for which the device is intended.

Examples:

The _____ is indicated for use in generating real time fluoroscopic images in patients where medically indicated.

The _____ is indicated for use in generating radiographic images of human anatomy. It is intended to replace a radiographic film/screen system in all general purpose diagnostic procedures.

B. Promotional Materials: All brochures and advertising copy that have been prepared to promote the use and sale of the device.

C. Instructions for Installation, Check-Out and Use:

1. User's Manual: A description of the methods for selection of the x-ray technique factors, image processing algorithms, and display settings (e.g. window width, window position, gray scale transfer characteristic, etc.) for the generation of the displayed image. All cautions, warnings, and contraindications associated with the use of the device. State the fill factor achieved by the device and indicate over what exposure range (and frame rates for fluoroscopic devices), if any, the device's operation is <u>not</u> quantum limited.

2. Ancillary Requirements: This information should include instructions on which particular display device(s) is appropriate and the method of using such display device(s) to achieve the intended use(s). A description, if applicable, of any instructions needed to obtain optimum images from either hard-copy (laser camera) or soft-copy (CRT) device(s) that will display the SSXI generated image.

D. Training Materials: To address the issue of how to account for the "learning curve" effect in the clinical utilization of an SSXI device, an approach to moving up the "learning curve" may be demonstrated by the use of a set of comprehensive training materials. A description of all training materials to be used by the manufacturer should be provided as part of the submission.

E. Documentation: In considering the total content of the labeling for this category of device, users should be provided with objective documentation of imaging performance from the manufacturers. Users can then employ this information in their evaluation of the importance of any tradeoffs between different characteristics of imaging performance. The documentation should include the data described in response to the Clinical and Nonclinical Considerations sections of this guidance encompassing: sensitometric response characteristics, spatial resolution properties, DQE, dynamic range and the display means utilized, the results of image tests, and typical patient doses. These data should also show the level of uncertainty associated with each measurement.

IX Quality Assurance Program

A submission should contain a complete description of the quality assurance program recommended to the user for maintaining the continued proper functioning of the SSXI device including its control hardware, software, and power supplies. The description should include the following information:

A. Parameter monitoring: A list of the parameters to be monitored and the procedures for and frequency of monitoring.

B. Quality criteria: A description of the standards, quality criteria, or limits of acceptance that are in place for each of the monitored parameters.

C. Manufacturers' records: A list of the records, with sample forms (if applicable) that the manufacturer will maintain for the QA program.

D. Q.A. training materials: A description of all training materials to be provided for performing, recording, and monitoring QA tests.