On June 14, 2023, FDA issued a guidance titled "Content of Premarket Submissions for Device Software Functions."[1] This final guidance supersedes the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued on May 11, 2005. The final guidance issued on June 14, 2023, provides information regarding the recommended documentation sponsors should include in premarket submissions for FDA's evaluation of the safety and effectiveness of device software functions. In particular, the final guidance includes information to help determine a device's Documentation Level (formerly known as Level of Concern). The purpose of the Documentation Level is to help identify the minimum amount of information that would support a premarket submission that includes device software functions.

Within the framework of the superseded guidance, display devices intended for diagnostic radiology were considered a device with a Minor Level of Concern. Based on the device's risk in the context of the device's intended use, as discussed in the final guidance "Content of Premarket Submissions for Device Software Functions," display devices intended for diagnostic radiology should generally address the recommendations for a Basic Documentation Level. The actual Documentation Level for your device may vary based on the specifics of your device. For more information about the Documentation Level and recommended documentation for a premarket submission, sponsors are encouraged to review the guidance "Content of Premarket Submissions for Device Software Functions."

[1] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-device-software-functions.

Contains Nonbinding Recommendations

Display Devices for Diagnostic Radiology

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 28, 2022.

Document originally issued on October 2, 2017.

This document supersedes the Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) Submissions issued May 30, 2008.

For questions about this document, contact RadHealth@fda.hhs.gov.

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

GRZAN

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2016-D-0270. 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 email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 1500022 and complete title of the guidance in the request.

GRZAN

Table of Contents

I. Introduction 1
II. Background 2
III. Scope 2
IV. Describing Your Device in a 510(k) 4
A. Indications for Use 4
B. Device Description 4
V. Electrical Safety 5
VI. Firmware and Software Documentation 6
VII. Physical Laboratory Testing 7
VIII. Labeling 8
Appendix 9
A. Performance Tests 10
B. Device Modifications 11
C. Device Bundling 11

GRZAN

Display Devices for Diagnostic Radiology

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The FDA is issuing this guidance to assist industry in preparing premarket notification (510(k)) submissions for display devices intended for use in diagnostic radiology.

This guidance is intended to apply to current technologies; however, FDA may request new or alternative test methods to fully evaluate the safety and effectiveness of future display technologies. In such instances, we recommend that you contact FDA to determine the appropriate regulatory pathway and testing for your device prior to submitting a 510(k). Please see Section III. Scope for more details on the types of devices covered by this guidance document.

For the current edition of the FDA-recognized consensus standards referenced in this document, see the FDA Recognized Consensus Standards Database.[1] For more information regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."[2]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.
[2] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

II. Background

This guidance applies to display devices intended for diagnostic radiology as identified in Section III. Scope, and currently classified under 21 CFR 892.2050 as class II devices.

This guidance document provides recommendations for the types of information you should provide in your 510(k) submission for display devices intended for diagnostic radiology. This information supplements the requirements for a 510(k) submission found in 21 CFR 807 Subpart E, as well as recommendations provided in other FDA documents concerning the specific content of a 510(k) submission, including FDA's guidance entitled, "Format for Traditional and Abbreviated 510(k)s"[3] and FDA's guidance entitled, "Refuse to Accept Policy for 510(k)s."[4]

This guidance supersedes a previously issued final guidance entitled "Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) Submissions" issued on May 30, 2008.

This guidance was revised with minor updates to reflect the issuance of the final rule, "Medical Devices; Medical Device Classification Regulations To Conform to Medical Software Provisions in the 21st Century Cures Act" (86 FR 20278).[5]

III. Scope

This document recommends what to include in a 510(k) submission for display devices in diagnostic radiology as identified by their classification regulation (21 CFR 892.2050) and product code (PGY). These devices are classified as class II devices that are intended to be used in controlled viewing conditions to display and view digital images for primary image interpretation. Display devices for diagnostic radiology may also be referred to as soft-copy displays or medical grade monitors. The classification regulation for these devices reads as follows:

21 CFR 892.2050 Medical image management and processing system

a) ***Identification.*** A medical image management and processing system is a device that provides one or more capabilities relating to the review and digital processing of medical images for the purposes of interpretation by a trained practitioner of disease detection, diagnosis, or patient management. The software components may provide advanced or complex image processing functions for image manipulation, enhancement, or quantification that are intended for use in the interpretation and analysis of medical images. Advanced image manipulation functions may include image segmentation, multimodality image registration, or 3D visualization. Complex quantitative functions

[3] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/format-traditional-and-abbreviated-510ks.
[4] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks.
[5] See 86 FR 20278 at https://www.federalregister.gov/documents/2021/04/19/2021-07860/medical-devices-medical-device-classification-regulations-to-conform-to-medical-software-provisions.

may include semi-automated measurements or time-series measurements.

b) ***Classification.*** Class II (special controls; voluntary standards – Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).

Typically, the 510(k) submission for display devices is separate from the 510(k) submissions of other image acquisition or management devices (e.g., hardware/software for image acquisition or image analysis). However, this guidance may apply when displays intended for diagnostic interpretation classified under 892.2050 (product code PGY) are included as part of a 510(k) submission along with other software and/or hardware.

This guidance does not apply to real-time displays that are part of the image acquisition device classified under other regulations (e.g., the display on a fluoroscopy system classified under 21 CFR 892.1650 (e.g., product codes JAA, OWB, OXO, QHY, and RCC) or the display on an ultrasonic pulsed Doppler imaging system classified under 21 CFR 892.1550 (e.g., product codes PSV, IYN, and NCS)).

This guidance does not apply to medical image hardcopy devices under 21 CFR 892.2040.

This guidance does not apply to imaging software and software applications. For information on these types of devices, please see FDA's guidance entitled "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices."[6]

This guidance does not apply to ophthalmic image management systems (product code NFJ) classified under 21 CFR 892.2050; medical cathode-ray tube (product code DXJ) classified under 21 CFR 870.2450; displays intended for whole-slide imaging and digital surgical or anatomical pathology; or displays for non-diagnostic applications in radiology (e.g., displays at the image acquisition workstation that are used by the technologist and not intended for diagnostic image review).

This guidance also does not apply to displays in handheld or mobile devices, a certain subset of which may be classified under 21 CFR 892.2050 (with product code PGY); for information on these types of devices see FDA's guidance entitled "Policy for Device Software Functions and Mobile Medical Applications."[7]

Sponsors may wish to submit a pre-submission to the appropriate review Division to receive guidance for displays not covered by this guidance. For information on FDA's pre-submission process, see FDA's guidance entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."[8]

---

[6] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices.
[7] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications.
[8] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.

If you are submitting a 510(k) for modification(s) to a cleared display or the same modification(s) apply to a number of display models, please refer to Appendices B. and C. for further information.

IV. Describing Your Device in a 510(k)

When submitting a 510(k) for the types of devices described in this guidance, you should identify your device by regulation and product code as described in Section III. Scope and include the information discussed below. You must provide information to FDA showing how your device is substantially equivalent (SE) to a predicate device (sections 513(f)(1) and 513(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)); 21 CFR 807.87(f)). We recommend that your 510(k) include the information described below, if applicable.

A. Indications for Use

The Indications for Use statement (IFU) should provide a general description of the disease(s) or condition(s) that your device will be used to help diagnose and the patient population for which the device is intended. The IFU should state whether your device is or is not intended for mammography. For instance, if your device is intended for mammography, including full-field digital mammography and digital breast tomosynthesis, your IFU should read as follows:

> The _____ is indicated for use in displaying radiological images (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners.

An example IFU if the device is not intended for mammography should read as follows:

> The _____ is indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography.

You should compare your device's IFU to the IFU of the predicate device, including any specific intended uses.

B. Device Description

We recommend that you provide a complete description of your device by including the information discussed below in your 510(k) submission. The items below should be presented in a tabular side-by-side comparison with the predicate device. The 510(k) submission should include a discussion of any differences in the technological characteristics between your device and the predicate device with additional information necessary to determine whether the differences raise new questions regarding the safety or effectiveness of the new device. Additional discussion in paragraph form is recommended for novel features. Your device description should include information such as the following:

- **Display Technology**: A description of the technological characteristics of the display device (e.g., in-plane switching liquid crystal display (LCD) panel with thin-film transistor (TFT) active-matrix array with cold cathode fluorescent lamp (CCFL) backlight).
- **Screen size**: A description of the physical size of the viewable area in diagonal and aspect ratio.
- **Backlight type (transmissive displays only)**: A description of the backlight type and, if substantially different from the predicate device, main properties, including temporal, spatial, and spectral characteristics.
- **Frame rate and refresh rate**: A description of the frame rate and refresh rate.
- **Pixel array, pitch, subpixel pattern, and pixel aperture ratio**: A description of the pixel array including pixel size, pixel pitch, and subpixel pattern (e.g., chevron, red, green, blue, and white (RGBW)).
- **Subpixel driving (spatial and temporal dithering)**: A description that indicates if the subpixels are used to improve gray-scale, temporal resolution, or spatial resolution.
- **Display Interface**: A description of the display interface (e.g., digital visual interface (DVI), display port, high-definition multimedia interface (HDMI)).
- **Video bandwidth**: A description of the capabilities of the information transfer pipeline between the image source and the digital driving levels in all associated components including the central processing unit (CPU)/graphics processing unit (GPU), graphics card, and display interface.
- **User controls**: A description of either the on-screen display (OSD) or software available for end users that relate to the display image quality (e.g., brightness and contrast controls, gamma, white point, power saving options, etc.).
- **Ambient light sensing**: A description of the ambient light sensing method, instrumentation, and software tool description.
- **Touch-screen technology**: A description of the method, functionality, and any calibration or periodical re-tuning requirements.
- **Luminance calibration tools**: A description of the sensor hardware and associated software for performing luminance calibration, and if applicable, details about the user-level procedures, service-action tolerances, and centralized automatic calibration tools.
- **Quality control procedures**: A description of the frequency and nature of quality-control tests to be performed by the user and/or the physicist with associated action limits. A detailed quality control manual should be included for regulatory review.
- **Software/Firmware**: A list with descriptions of any additional firmware or software features for image manipulation or analysis and color management (if applicable) not covered by any of the above items.

For further detail related to the recommended content of each item above, please refer to Appendix A.

V. Electrical Safety

You should evaluate the electrical safety of your device according to one or more of the most recent FDA-recognized version of the following consensus standards, or any equivalent method being used as an alternative to evaluate electrical safety:

- ANSI/AAMI ES60601-1 *Medical electrical equipment: Part 1: General requirements for basic safety and essentional performance*

For 510(k) submissions for display devices intended for diagnostic radiology, in lieu of providing the actual electric safety test reports, you may simply submit a Declaration of Conformity to an FDA-recognized consensus standard to indicate that your device has been tested for compliance with the appropriate consensus standards. FDA may request to review the actual test reports if the IFU, device description, and/or labeling for your device raises concerns regarding the electrical safety. The features and design of your device will determine whether other consensus standards are appropriate in addition to, or in place of the consensus standards provided above. For more information on the use of consensus standards, please refer to section 514(c)(1)(B) of the FD&C Act and FDA's website on the Standards and Conformity Assessment Program.[9]

VI. Firmware and Software Documentation

Display devices intended for diagnostic radiology may include firmware and software for the following functionalities:

- Display controls,
- Ambient light sensing,
- Luminance calibration tools, and/or
- Quality-control software.

Your 510(k) submission should include documentation for the software and firmware that you have developed for use with your device. The kind of information that we recommend you submit in your 510(k) is determined by the "level of concern," which is based on the risks associated with a potential software failure by your device. If the software/firmware is limited to the four functionalities listed above, the level of concern may be considered minor. If your device submission introduces or modifies more advanced software features than those features listed above, you should consider contacting the relevant branch chief or submitting a Pre-Submission to request FDA's feedback on whether the software would be a minor, moderate, or major level of concern. In most instances, the software documentation may be submitted in your 510(k) at a minor level of concern. When preparing the software documentation for your 510(k) submission and for guidance on what information you should include based on the level of concern, please see the following FDA guidance documents:

[9] Available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program.

- "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices;"[10]
- "General Principles of Software Validation;"[11]
- "Off-the-Shelf Software Use in Medical Devices;"[12]
- "Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software;"[13] and
- "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices."[14]

VII. Physical Laboratory Testing

We recommend that you provide the following performance testing data with a side-by-side comparison of technical performance testing data to the predicate device in your 510(k) submission. Table 1 below identifies what tests we recommend you perform in demonstrating substantial equivalence to a predicate device based on the IFU of your display device (Table 1 includes recommendations for both non-mammography and mammography intended uses). Please refer to Appendix A. for additional guidance on each test and references for methods and procedures for display characterization.

Table 1. Recommended Physical Laboratory Tests

Measurements	Recommended for Non-mammography Display Submissions	Recommended for Mammography Display Submissions
a. Spatial resolution	Yes	Yes
b. Pixel defects (maximum counts, allowed defect types, and locations)	Yes	Yes
c. Artifacts	Yes	Yes
d. Temporal response	Yes (Limited)	Yes
e. Luminance (maximum, minimum, achievable, and recommended)	Yes	Yes
f. Conformance to a grayscale-to-luminance function (e.g., DICOM GSDF)	Yes	Yes

[10] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices.
[11] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-principles-software-validation.
[12] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-software-use-medical-devices.
[13] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-networked-medical-devices-containing-shelf-ots-software.
[14] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0.

Measurements	Recommended for Non-mammography Display Submissions	Recommended for Mammography Display Submissions
g. Luminance at 30° and 45° in diagonal, horizontal, and vertical directions at center and four corners	No	Yes
h. Luminance uniformity or Mura test	No	Yes
i. Stability of luminance and chromaticity response with temperature and time of operation or on-time	No	Yes
j. Spatial noise	No	Yes
k. Reflection coefficient	No	Yes
l. Veiling glare or small-spot contrast	No	Yes
For color displays, the following measurements should also be reported:		
m. Color tracking (primary colors and color gamut)	Yes	Yes
n. Gray tracking (gray shades and white point)	No	Yes

We recommend that you include a brief description of the test method(s) you have used to address each performance aspect identified in Table 1 above. If you follow a suggested test method, you may cite the method rather than describing it in your 510(k) submission. If you modify a suggested test method, you may cite the method, but should provide sufficient information to explain the nature of and reason for the modification. We recommend that you provide a description of all proprietary measurement systems used for performing quantitative tests, including the trade name, characteristics, and accuracy of the measurement tools.

For cases where the new device performs significantly lower than the predicate device on one or more of the physical laboratory tests in Table 1, an additional study that further characterizes underperforming features of the display may be necessary to demonstrate substantial equivalence to a predicate device.

VIII. Labeling

The following Section is intended to assist you in preparing labeling that satisfies FDA's labeling requirements under 21 CFR Part 801.[15]

A prescription device in compliance with 21 CFR 801.109 is exempt from section 502(f)(1) of the FD&C Act that requires adequate directions for use by a lay person. As a prescription device, your device must meet the labeling requirements for prescription devices under 21 CFR 801.109, including a prescription use statement.

[15] Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of 21 CFR Part 801.

Your 510(k) submission must include proposed labels, labeling, and advertisements in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). We recommend that you submit clear and concise instructions for use that delineate the technological features of your device and how your device is to be used. Instructions should encourage local/institutional training programs designed to familiarize users with the features of your device and instruct users on how to use your device in a safe and effective manner.

FDA recommends that the labeling for review workstation displays intended for mammography include the following statement:

> Mammographic images with lossy compression must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA.

In addition to meeting any requirements under 21 CFR Part 801, your device's user manual should include the following information, as appropriate:

- IFU as stated in your premarket submission;
- Warnings and precautions (and any mitigation measures);
- Overview of the device;
- Principles of operation;
- Directions for use (e.g., display controls and graphical user interface (GUI));
- Technical specifications;
- Performance specifications (summary of physical laboratory testing);
- Cleaning information;
- Hardware/software compatibility requirements;
- Conformity to any voluntary consensus standards; and
- Manufacturer's contact information.

In addition, instructions for maintenance of the system performance (quality assurance processes) should include:

- A description of personnel authorized to service the system;
- Recommended maintenance schedule;
- Calibration procedures; and
- A full description of recommended quality assurance testing (with action limits), including detailed procedures for performing these tests, if applicable, and the frequency of testing. You may use the latest recognized consensus standards version of NEMA XR 22: *"Quality Control Manual" Template for Manufacturers of Displays and Workstations Labeled for Final Interpretation in Full-Field Digital Mammography (FFDM)* for designing quality assurance tests.

Appendix

A. Performance Tests

The following provides additional details on the individual tests recommended in Section VII. Physical Laboratory Testing, along with an explanation of what information should be included for each test.

a. ***Spatial resolution***: Measurements of the transfer of information from the image data to the luminance fields at different spatial frequencies of interest typically done by reporting the modulation transfer function. Non-isotropic resolution properties should be characterized properly by providing two-dimensional measurements or measurements along at least two representative axes.
b. ***Pixel defects***: Measurements (count, types (e.g., sub-pixel or entire pixel, always-on, always-off), and locations (map)) of pixel defects. This is typically provided as a tolerance limit. Pixel defects can interfere with the visibility of small details in medical images.
c. ***Artifacts***: Evaluate for image artifacts such as ghosting and/or image sticking from displaying a fixed test pattern for a period of time.
d. ***Temporal response***: Measurements of the temporal behavior of the display in responding to changes in image values from frame to frame. Since these transitions are typically not symmetric, rise and fall time constants are needed to characterize the system. Slow displays can alter details and contrast of the image when large image stacks are browsed or in video, panning, and zooming modes.
    a. *For non-mammography displays*, you should measure the rise and fall time constants for 5–95% and 40–60% luminance transitions.
    b. *For mammography displays*, you should measure the rise and fall time constants at several (e.g., every 15 levels) grayscale intervals between 0 and 255.
e. ***Maximum and minimum luminance (achievable and recommended)***: Measurements of the maximum and minimum luminance that the device outputs as used in the application under recommended conditions and the achievable values if the device is set to expand the range to the limit.
f. ***Conformance to a grayscale-to-luminance function (e.g., DICOM GSDF)***: Measurements of the mapping between image values and the luminance output following a target model response for 256 or more levels.
g. ***Luminance at 30° and 45° in diagonal, horizontal, and vertical directions at center and four corners***: Measurements of the luminance response at off-normal viewing related to the target model for the luminance response.
h. ***Luminance uniformity or Mura test***: Measurements of the uniformity of the luminance across the display screen.
i. ***Stability of luminance and chromaticity responses with temperature and time of operation (on-time)***: Measurements of the change in luminance and chromaticity response with temperature and use time.
j. ***Spatial noise***: Measurements of the spatial noise level as represented by the noise power spectrum using an appropriate ratio of camera and display pixels. Spatial noise and resolution affect the way images are presented to the viewer and can alter features that are relevant to the interpretation process of the physician or radiologist.

k. ***Reflection coefficients***: Measurements of the reflection coefficients of the display device. Specular and diffuse reflection coefficients can be used as surrogates for the full bidirectional reflection distribution function.
l. ***Veiling glare or small-spot contrast***: Measurements of the contrast obtained for small targets.
m. ***Color tracking***: Chromaticity at different luminance levels of primary colors as indicated by the color coordinates in an appropriate units system (e.g., CIE u'v') and the color gamut enveloped by the primary colors.
n. ***Gray tracking***: Chromaticity at different luminance levels of gray shades, including the white point, as indicated by the color coordinates in an appropriate units system (e.g., CIE u'v') (see the recognized version of IEC 62536-1 *Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods*, and ISO/CIE 11664-5 *Colorimetry - Part 5: CIE 1976 L*u*v* colour space and u', v' uniform chromaticity scale diagram*).

For device description as well as testing methods and procedures for display characterization, please refer to the following:

- Samei, E., et al., Assessment of display performance for medical imaging systems: Executive summary of AAPM TG18 Report. Medical Physics, 2005. 32(4):1205-1225. https://doi.org/10.1118/1.1861159.
- International Electrotechnical Commission IEC 62536-1 *Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods*; and
- International Committee for Display Metrology (ICDM). *Information Display Measurements Standard (IDMS)*. http://www.icdm-sid.org.

B. Device Modifications

We recommend that you refer to FDA's guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"[16] for subsequent models of the same device family that have previously received 510(k) clearance. You should perform regression testing and physical laboratory testing in conformance with the relevant test consensus standards to verify that the changes did not adversely impact image quality and ensure that the device conforms to specifications as required under the Quality System Regulation (21 CFR 820.70). For example, changes in the graphics driver, power supply, or upgrade in the calibration software are unlikely to affect the safety and effectiveness of the device, and thus, such changes are unlikely to require a new 510(k) submission under 21 CFR 807.81(a)(3), but sponsors should review the appropriate regulations and consensus standards to determine whether a new 510(k) submission is necessary. Sponsors should contact the appropriate FDA review Division with any questions about modifications made to their devices.

C. Device Bundling

[16] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device.

Often, firms may make the same modification(s) to all of their display models. Instead of submitting a separate 510(k) submission for each display model, FDA recommends submitting a bundled submission for all impacted display models. Bundling is appropriate for devices that present scientific and regulatory issues that can most efficiently be addressed during one 510(k) submission review. For more information, please refer to FDA's guidance entitled "Bundling Multiple Devices or Multiple Indications in a Single Submission."[17]

[17] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bundling-multiple-devices-or-multiple-indications-single-submission.