August 31, 2026

Siemens Medical Solutions USA, Inc.
% Anntina Walker
Regulatory Affairs Professional
40 Liberty Blvd.
MALVERN, PA 19355

Re: K260488
Trade/Device Name: MULTIX Impact; MULTIX Impact C
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: July 27, 2026
Received: July 27, 2026

Dear Anntina Walker:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260488

Please provide the device trade name(s).

MULTIX Impact;
MULTIX Impact C

Please provide your Indications for Use below.

MULTIX Impact is a radiographic system used in hospitals, clinics, and medical practices. MULTIX Impact enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. Exposures may be taken with the patient sitting, standing, or in the prone position. MULTIX Impact is not intended for mammography.
MULTIX Impact uses digital detectors for generating diagnostic images by converting X- rays into image signals. MULTIX Impact is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.

MULTIX Impact C is a radiographic system used in hospitals, clinics, and medical practices. MULTIX Impact C enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. Exposures may be taken with the patient sitting, standing, or in the prone position. MULTIX Impact C is not intended for mammography.
MULTIX Impact C uses digital detectors for generating diagnostic images by converting X- rays into image signals. MULTIX Impact C is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary:
MULTIX Impact / MULTIX Impact C
K260488

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355

Date Prepared: August 28, 2026

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. General Information

Importer/ Distributor
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Establishment Registration Number: 2240869

Location of Manufacturing Site
Siemens Shanghai Medical Equipment Ltd.
278 Zhou Zhu Road
Shanghai, 201318, China
Establishment Registration Number: 3003202425

Siemens Healthineers AG
Siemensstrasse 1
Forchheim, Germany 91301
Establishment Registration Number: 3004977335

2. Contact Person

AnnTina Walker
Regulatory Affairs Professional
Siemens Medical Solutions USA, Inc.
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Malvern, PA 19355
+1 6174356938
anntina.walker@siemens-healthineers.com

3. Subject Device Name and Classification

Trade Name:	MULTIX Impact
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR, MQB

Trade Name:	MULTIX Impact C
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR, MQB

4. Legally Marketed Predicate/Reference Devices

Trade Name:	MULTIX Impact
510(k) #:	K213700
Clearance Date:	December 13, 2021
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR, MQB

Trade Name:	MULTIX Impact C
510(k) #:	K213700
Clearance Date:	December 13, 2021
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR, MQB

5. Device Description

The MULTIX Impact Radiography X-ray system is a floor mounted, modular system of x-ray components (x-ray tube, bucky wall stand, patient table, x-ray generator, portable wireless and fixed detectors) based on the predicate device, the MULTIX Impact (K213700).

The MULTIX Impact C Radiography X-ray system is a ceiling suspended, modular system of x-ray components (x-ray tube, bucky wall stand, patient table, x-ray generator, portable wireless and fixed detectors) based on the predicate device, the MULTIX Impact C (K213700). There's no differences between the models MULTIX Impact and MULTIX Impact C, besides how they attach to the floor or ceiling, respectively.
The following modifications have been made to the predicate devices:

1. New hardware: Desktop PC and Display, Scalance W763 AP, Wireless Remote-Control Console (improved version), Power Supply Unit, Wall Charger.
2. Software modification: Windows 10 update from 2016 to 21H2, In-house ortho algorithm, Workflow improvement. The device software platform was previously cleared with the predicate system under K213700. The changes in this submission are limited to software updates to the cleared platform, including operating system update, workflow improvements, and an upgraded ortho stitching/registration algorithm.
3. New configuration option: Integrate Non-tilting wall stand for MULTIX Impact C. This configuration option is the only additional hardware configuration difference specific to MULTIX Impact C beyond the ceiling-suspended mounting architecture described above.
4. Modifications will also be offered as an optional upgrade kit for the predicate devices, MULTIX Impact (K213700) and MULTIX Impact C (K213700)
5. The flat-panel detectors used to acquire images remain detectors previously cleared with the predicate systems, and no additional x-ray detectors are being introduced.
6. In-house ortho algorithm is a new algorithm to realize the ortho stitch feature which has no change from predicate devices. Verification activities covering both functionality and performance have been conducted to ensure that the upgraded software has been adequately tested for effectiveness.

6. Indications for Use

MULTIX Impact:
MULTIX Impact is a radiographic system used in hospitals, clinics, and medical practices. MULTIX Impact enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients.
Exposures may be taken with the patient sitting, standing, or in the prone position. MULTIX Impact is not intended for mammography.

MULTIX Impact uses digital detectors for generating diagnostic images by converting X- rays into image signals. MULTIX Impact is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.

MULTIX Impact C:
MULTIX Impact C is a radiographic system used in hospitals, clinics, and medical practices. MULTIX Impact C enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. Exposures may be taken with the patient sitting, standing, or in the prone position. MULTIX Impact C is not

intended for mammography.

MULTIX Impact C uses digital detectors for generating diagnostic images by converting X- rays into image signals. MULTIX Impact C is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.

7. Substantial Equivalence

MULTIX Impact:
MULTIX Impact is a modification of the predicate device, the MULTIX Impact, cleared via K213700. The subject device is within the same classification regulation, has the same indications for use, and the same mechanical design as the predicate device. The MULTIX Impact is substantially equivalent to the predicate device and documentation is provided to support a claim of substantial equivalence.

MULTIX Impact C:
MULTIX Impact C is a modification of the predicate device, the MULTIX Impact C, cleared via K213700. The subject device is within the same classification regulation, has the same indications for use, and the same mechanical design as the predicate device. The MULTIX Impact C is substantially equivalent to the predicate device and documentation is provided to support a claim of substantial equivalence.

8. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device

The subject devices are substantially equivalent to the predicate devices in terms of the indications for use, design, material, functionality, technology, and energy source. The subject devices use the same or similar components cleared in the predicate devices.

The components of the subject device have many of the same technological characteristics as those in the predicate device. Some technological characteristics that differ slightly are shown in attached comparison table. Verification and validation testing have been successfully completed and test results show that the subject devices with all its components is substantially equivalent to the predicate devices.

The modifications made to the subject devices do not affect the intended use of the device nor do they alter its fundamental scientific technology compared to the predicate devices.

The following tables compare the main performance data of the subject device with the predicate device.

Table 1: Indications for Use Comparison

Attribute	MULTIX Impact (Subject)	MULTIX Impact K213700 (Predicate)	Comparison Results
Indications for Use	MULTIX Impact is a radiographic system used in hospitals, clinics, and medical practices. MULTIX Impact enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. Exposures may be taken with the patient sitting, standing, or in the prone position. MULTIX Impact is not intended for mammography. MULTIX Impact uses digital detectors for generating diagnostic images by converting X- rays into image signals. MULTIX Impact is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.	MULTIX Impact is a radiographic system used in hospitals, clinics, and medical practices. MULTIX Impact enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. Exposures may be taken with the patient sitting, standing, or in the prone position. MULTIX Impact is not intended for mammography. MULTIX Impact uses digital detectors for generating diagnostic images by converting X- rays into image signals. MULTIX Impact is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.	**Same**

Attribute	MULTIX Impact C (Subject)	MULTIX Impact C K213700 (Predicate)	Comparison Results
Indications for Use	MULTIX Impact C is a radiographic system used in hospitals, clinics, and medical practices. MULTIX Impact C enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. Exposures may be taken with the patient sitting, standing, or in the prone position. MULTIX Impact C is not intended for mammography.	MULTIX Impact C is a radiographic system used in hospitals, clinics, and medical practices. MULTIX Impact C enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. Exposures may be taken with the patient sitting, standing, or in the prone position. MULTIX Impact C is not intended for mammography.	**Same**

	MULTIX Impact C uses digital detectors for generating diagnostic images by converting X- rays into image signals. MULTIX Impact C is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.	MULTIX Impact C uses digital detectors for generating diagnostic images by converting X- rays into image signals. MULTIX Impact C is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.	

Table 2: Subject Device Compared to Predicate Device

Attribute	MULTIX Impact (Subject) MULTIX Impact C (Subject)	MULTIX Impact K213700 (Predicate) MULTIX Impact C K213700 (Predicate)	Comparison Results
Generator	Polydoros RFX	Polydoros RFX	**Same**
X-ray Tube	RAY-14S_3F	RAY-14S_3	**Same**
Collimator	- Collimator ML03 - Collimator RFU	- Collimator ML03 - Collimator AL04 - Collimator RFU	**Same**
	- Collimator RFU	- Collimator AL04 - Collimator RFU	
Detector	- Trixell Pixium 3543EZH (MAX wi-D) - iRay Mars1717VS (Core XL) - iRay Venu1717X (Core Static)	- Trixell Pixium 3543EZH (MAX wi-D) - iRay Mars1717VS (Core XL) - iRay Venu1717X (Core Static)	**Same**
Bucky wall stand	Manual or motorized vertical module	Manual or motorized vertical module	**Same**
	- Motorized vertical module - Manual tilting module	- Motorized vertical module - Manual tilting module	
Floor mounted tube stand (MULTX Impact)	Floor mounted semi-motorized - - Manual tube tilting - Manual longitudinal movement Floor mounted fully motorized - Manual tube tilting - Motorized tube lifting - Manual longitudinal movement - Motorized tube tilting - Motorized longitudinal	Floor mounted semi-motorized - Manual tube tilting - Manual longitudinal movement Floor mounted fully motorized - Manual tube tilting - Motorized tube lifting - Manual longitudinal movement - Motorized tube tilting - Motorized longitudinal	**Same**

Attribute	MULTIX Impact (Subject) MULTIX Impact C (Subject)	MULTIX Impact K213700 (Predicate) MULTIX Impact C K213700 (Predicate)	Comparison Results
Ceiling suspension tube stand (MULTX Impact C)	Ceiling suspension manual - Manual tube tilting - Motorized tube lifting Ceiling suspension motorized - Motorized tube tilting - Motorized tube lifting	Ceiling suspension manual - Manual tube tilting - Motorized tube lifting Ceiling suspension motorized - Motorized tube tilting - Motorized tube lifting	**Same**
All-in-one PC	- With touch screen - With non-touch screen	- With touch screen - With non-touch screen	**Same**
Desktop PC and display	Desktop PC and separate display (Touch screens are available as an option.)	N.A.	**Different** Phase in new PC and display V&V test concluded with no impact on safety and effectiveness.
Patient table	Elevating patient table with tray for wireless or fixed detector	Elevating patient table with tray for wireless or fixed detector	**Same**
Imaging System	Software version: VA21	Software version: VA21	**Different** Software update for bugfix and improvement, including Windows 10 update, in-house ortho algorithm and workflow improvement. V&V test and bench testing concluded with no impact on safety and effectiveness.
HMI (Human Machine Interface)	Remote Interface supported by Siemens provided tablet that meets minimum requirements. Smart Remote Control (SRC) supported by Siemens provided Phone that meets minimum requirements.	Remote Interface supported by Siemens provided tablet that meets minimum requirements. Smart Remote Control (SRC) supported by Siemens provided Phone that meets minimum requirements.	**Same**

Attribute	MULTIX Impact (Subject) MULTIX Impact C (Subject)	MULTIX Impact K213700 (Predicate) MULTIX Impact C K213700 (Predicate)	Comparison Results
Camera	3D Camera	2D Camera 3D Camera	**Same**
Ortho	Stitching images for long leg or Full Spine	Stitching images for long leg or Full Spine	**Different** The functionality is the same but additionally phase in a new algorithm. V&V test and bench testing concluded with no impact on safety and effectiveness.
AI-based Auto Thorax Collimation	Exam range automatically planned for Thorax by 3D camera with manual adjustment	Exam range automatically planned for Thorax by 3D camera with manual adjustment	**Same**
AI-based Auto TOD Measurement	The table-to-object distance (TOD value) automatically detected for Ortho examinations.	The table-to-object distance (TOD value) automatically detected for Ortho examinations.	**Same**
AI-based Auto Full-Spine & Long-Leg Collimation	Otho range automatically planned for Full-Spine & Long-Leg by camera with manual adjustment.	Otho range automatically planned for Full-Spine & Long-Leg by camera with manual adjustment.	**Same**

9. Nonclinical Performance Testing

Non-clinical tests were conducted for the MULTIX Impact and MULTIX Impact C during product development. The modifications described in this Premarket Notification are supported with verification and validation testing.

MULTIX Impact and MULTIX Impact C conforms to the following standards:

ANSI ES60601-1:2005/(R)2012 and A1:2012 and A2: 2021
IEC 60601-1-2 Edition 4.1 2020-09
IEC 60601-1-3 Edition 2.1 2021-01
IEC 62366-1 Edition 1.0 2020-06

ISO 14971 Second edition 2019-12
IEC 60601-1-6 Edition 3.2 2020-07
IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION
IEC 60601-2-28 Edition 3.0 2017-06
IEC 60601-2-54 Edition 2.0 2022-09
NEMA PS 3.1 - 3.20 (2024e)
ISO 10993-1 Fifth edition 2018-08
IEC TS 60601-4-2 Edition 2024-03

Software Documentation for a Basic Level of Concern software per FDA's Guidance Document *Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration* Staff, issued on June 14, 2023, is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. Non-clinical tests (integration and functional) were conducted on the MULTIX Impact and MULTIX Impact C during product development.

The effectiveness of new algorithm for ortho stitch has been demonstrated through completed performance testing and functionality testing under representative use conditions. The performance testing evaluated stitching accuracy and stitching uniformity and confirmed that the algorithm achieves the intended stitching performance for long-leg and full-spine examinations. The functionality testing verified that the algorithm is properly integrated into the software workflow and performs as intended.

Cybersecurity testing has also been completed for the subject devices. Cybersecurity requirements were verified as part of system integration testing. Static code analysis and vulnerability scanning were performed to identify potential cybersecurity weaknesses. In addition, third-party penetration testing, including fuzz testing and vulnerability scanning, was completed on the software version intended for clearance. Identified cybersecurity risks were evaluated and mitigated as appropriate.

General Safety and Effectiveness Concerns
Instructions for use are included within the device labeling and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features, including visual and audible warnings, are incorporated into the system design. In addition, MULTIX Impact and MULTIX Impact C Radiography X-ray system are continually monitored and if an error occurs the system functions will be blocked and an error message will be displayed.

Risk management is ensured via a hazard analysis which is used to identify potential hazards. These potential hazards are controlled via software development, verification, and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing. Furthermore, the operators are healthcare

professionals familiar with and responsible for the x-ray examinations to be performed.

10. Conclusion as to Substantial Equivalence

The MULTIX Impact / MULTIX Impact C has the same indications for use as the predicate device, MULTIX Impact (K213700) / MULTIX Impact C (K213700). The operating environment and mechanical design are similar.

Verification and validation testing demonstrate that the MULTIX Impact and MULTIX Impact performs as intended. The non-clinical test data demonstrate that the MULTIX Impact and MULTIX Impact C device performance is comparable to the predicate device that is currently marketed for the same intended use.

In summary, Siemens concludes that the MULTIX Impact and MULTIX Impact does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate device, MULTIX Impact (K213700) and MULTIX Impact C (K213700).

11. Guidance documents

The following FDA guidance documents were utilized in the documentation of this Premarket Notification:

- *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*
  Document issued on: June 27, 2025

- *Electromagnetic Compatibility (EMC) of Medical Devices Guidance for Industry and Food and Drug Administration Staff*
  Document issued on June 6, 2022.

- *Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff*
  Document issued on November 28, 2017.

- *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices Guidance for Industry and Food and Drug Administration Staff*
  Document issued on: September 1, 2016

- *Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration Staff*
  Document issued on: June 14, 2023

- *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices Guidance for Industry and Food and Drug Administration Staff*
  Document issued on: September 14, 2018

- *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food and Drug Administration Staff*
  Document issued on: July 28, 2014

- *Radio Frequency Wireless Technology in Medical Devices Guidance for Industry and Food and Drug Administration Staff*
  Document issued on: August 14, 2013