June 12, 2026

Konica Minolta Healthcare Americas, Inc.
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES, FL 34114

Re: K252996
Trade/Device Name: Universal 1417PI
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB, LLZ
Dated: April 1, 2025
Received: September 18, 2025

Dear Daniel Kamm:

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
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological 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.	K252996

Please provide the device trade name(s).

Universal 1417PI

Please provide your Indications for Use below.

This device is indicated for use in generating radiographic images of human anatomy. It is intended to a replace radiographic film/screen system in general-purpose diagnostic procedures. This device is not indicated for use in mammography, fluoroscopy, and angiography applications.

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

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

510(k) #: K252996

510(k) Summary

Prepared on: 2026-05-13

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Konica Minolta Healthcare Americas, Inc.
Applicant Address	2217 US Highway 70 East Garner NC 27529 United States
Applicant Contact Telephone	800.934.1034
Applicant Contact	Ms. Jan Maniscalco
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Correspondent Name	Kamm & Associates
Correspondent Address	8870 Ravello Ct Naples FL 34114 United States
Correspondent Contact Telephone	847-374-1727
Correspondent Contact	Mr. Daniel Kamm
Correspondent Contact Email	fda.help.now@gmail.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Universal 1417PI
Common Name	Stationary x-ray system
Classification Name	Stationary X-ray system
Regulation Number	892.1680
Product Code(s)	MQB LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K214030	Universal DR 1748	MQB

Device Description Summary

21 CFR 807.92(a)(4)

Konica Minolta Universal 1417PI combines components into a complete digital x-ray system upgrade kit, including software and digital radiography panel. The indications for use remains unchanged: This device is indicated for use in generating radiographic images of human anatomy. It is intended to a replace radiographic film/screen system in general-purpose diagnostic procedures. This device is not indicated for use in mammography, fluoroscopy, and angiography applications. So the only difference between this submission and the predicate submission is the size and resolution of the digital receptor panel. The software has not changed materially since it was last cleared. Each system consists of the following items: Customer supplies: Diagnostic x-ray generator (HF) + Tubehead + Tube Mount + Attached Manual Collimator

We supply: Digital X-Ray Receptor Panel 892.1680 Class II Code MQB, and Digital X-ray Software. The software offered for sale with this system has received previous 510(k) clearance in K212291. Besides the upgraded flat-panel detector, all components of the stationary x-ray system are left unchanged.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

This device is indicated for use in generating radiographic images of human anatomy. It is intended to a replace radiographic film/screen system in general-purpose diagnostic procedures. This device is not indicated for use in mammography, fluoroscopy, and angiography applications.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use statement has not changed. This submission represents the addition of a new compatible digital x-ray receptor panel. The software remains the same as it was in its most recent clearance. Additional cybersecurity information is supplied.

Technological Comparison

21 CFR 807.92(a)(6)

The technological characteristics remain essentially the same, just the digital receptor panel size has changed. Updated cybersecurity information is prvided.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

We performed electrical safety testing, EMC testing, and a clinical image evaluation report showing that diagnostic quality images could be obtained. The images were reviewed by a Board Certified Radiologist.

After analyzing bench test results, risk analysis, and clinical evaluation, it is the conclusion of Konica Minolta LLC that the Konica Minolta Universal 1417PI upgrade kit is as safe and effective as the predicate device, has few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.