Konica Minolta, Inc.
% Jan Maniscalco
Executive Vice President QA/RA
Konica Minolta Healthcare Americas, Inc.
411 Newark Pompton Turnpike
Wayne, New Jersey 07470

May 31, 2024

Re: K240281
Trade/Device Name: Bone Suppression Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 1, 2024
Received: May 1, 2024

Dear Jan Maniscalco:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240281

Device Name
Bone Suppression Software

Indications for Use *(Describe)*
Bone Suppression Software is an image processing technology to improve the visibility of soft tissues in the lung area by suppressing the signals of ribs and clavicles in chest x-ray images.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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KONICA MINOLTA

510(k) Summary K240281

Complying with 21 CFR R §807.92.

I. SUBMITTER

KONICA MINOLTA, INC.
1 Sakura-machi, Hino-shi,
Tokyo, 191-8511, Japan

Contact Person: Tsutomu Fukui
Phone: +81-42-589-8429
Email: tsutomu.fukui1@konicaminolta.com
Date Prepared: February 1st, 2024

II. DEVICE

Name of Device: Bone Suppression Software
Common Name: Radiological Image Processing Software
Classification Name: Medical Image Management and Processing System (21 CFR 892.2050)
Regulatory Class: Class II
Product Code: LLZ

III. PREDICATE DEVICES

Predicate Device: ImagePilot, K210066
Reference Device: Bone Suppression Software, K133442

IV. DEVICE DESCRIPTION

The purpose of this software is to provide Bone Suppression images. The software receives the exposed frontal plain chest X-ray images as inputs, then starts processing each image from the Senciafinder Gateway application. After the software is started, it performs the extraction process of the lung field area and Bone Suppression process to attenuate the signals of bones, and outputs Bone Suppression images with attenuated signals of ribs and clavicles in the extracted lung field area.

In conjunction with the Senciafinder Gateway, images are received from diagnostic imaging equipment via network. Received images are applied Bone Suppression processing and output to image display system such as PACS / workstation via network.

V. INDICATIONS FOR USE

Bone Suppression Software is an image processing technology to improve the visibility of soft tissues in the lung area by suppressing the signals of ribs and clavicles in chest x-ray images.

The Indications for Use statement for the Bone Suppression Software is similar to the reference device. The differences do not alter the intended use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for the function of the bone suppression software, by suppressing the signals of the ribs and clavicles in chest x-ray images.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The bone suppression function is available as an integrated optional function within the predicate device. The purpose of the subject device is to be available as a single image processing software device. The subject and predicate devices are based on the same technology to create bone suppression images by attenuating signals from ribs and clavicles in the extracted lung field area.

The following technological differences exist between the subject and predicate devices:

- The subject device must be used in conjunction with the Senciafinder Gateway whereas the predicate device has a bone suppression function incorporated into the system
- Use of CR/DR images from own and other vendors.

VII. PERFORMANCE DATA

All the verification and validation activities required by the specification and the risk analysis for the Bone Suppression Software were performed and the results showed that the predetermined acceptance criteria were met. No clinical studies were required to support the substantial equivalence.

Software Verification and Validation

Software Verification and Validation Testing Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions." The software for this device was considered as a "Basic Documentation Level" since a failure or latent flaw of the software function would not present a hazardous situation with a probable risk of death or serious injury to the patient or operator.

VIII. CONCLUSIONS

The technological differences do not raise different issues of safety and/or effectiveness as compared to its predicate device (K210066). Performance testing demonstrates that the Bone Suppression Software performs as specified and functions as intended. It is concluded that the subject device is as safe and effective as the predicate and is substantially equivalent to the predicate device.