July 31, 2026

Radiaction , Ltd.
% Yossi Muncher
Official Correspondent
Hanechoshet 10
Floor 5
TEL AVIV, 6971072
ISRAEL

Re: K260607
Trade/Device Name: Shield System (Siemens 30x40)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB
Dated: July 2, 2026
Received: July 2, 2026

Dear Yossi Muncher:

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,

FDA Digitally signed by GABRIELA M. RODAL -S for

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

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)*
K260607

Device Name
Shield System (Siemens 30x40)

Indications for Use *(Describe)*
Radiaction's Shield System is intended for reducing unnecessary exposure to scatter X-ray radiation of medical teams during fluoroscopy-guided-procedures with the Toshiba Infinix-I or Siemens Artis C-arm, by attenuating scatter radiation. It is not intended to be used with such procedures for head and neck areas.

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.

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510(k) #: K260607

510(k) Summary

Prepared on: 2026-07-02

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Radiaction Ltd.
Applicant Address	Hanechoshet 10 Floor 5 Tel Aviv 6971072 Israel
Applicant Contact Telephone	+972508580308
Applicant Contact	Dr. Yossi Muncher
Applicant Contact Email	raqa@radiactionmedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Shield System (Siemens 30x40)
Common Name	Interventional Fluoroscopic X-Ray System
Classification Name	Image-intensified fluoroscopic x-ray system
Regulation Number	892.1650
Product Code(s)	OWB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222625	Shield System	OWB

Device Description Summary

21 CFR 807.92(a)(4)

Radiaction's Shield System is designed to improve the safety and efficiency of the medical team performing image-guided procedures in the interventional suite, by reducing their exposure to scatter X-ray radiation. The Shield System technology blocks the scatter radiation close to its source by creating an attenuating barrier around the direct imaging beam. The barriers surround the beam between the C-arm source and table (below the table) and between the patient and the C-arm detector (above the table) blocking scatter radiation resulting from the imaging beam's interface with both the patient and the table.

The system is assembled on a commercially available fixed C-arm system using a designated connection unit but remains independent and does not require any direct power or data interface with the C-arm.

The Shield System includes a support station, two dynamic radiation shielding units ("Shields"), a user control panel, an indication panel, a patient Face Guard and patient covers (femoral and radial). The upper shield is fixed to the C-arm around the detector and the lower shield is placed around the x-ray source. Both shields are assembled to the C-arm using a designated connection unit.

All of the device's sub-systems (excluding the Face Guard and patient covers) are connected to and governed from the support station, which can be positioned anywhere in the room.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Radiaction's Shield System is intended for reducing unnecessary exposure to scatter X-ray radiation of medical teams during fluoroscopy-guided-procedures with the Toshiba Infinix-I or Siemens Artis C-arm, by attenuating scatter radiation. It is not intended to be used with such procedures for head and neck areas.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are the same.

Technological Comparison

21 CFR 807.92(a)(6)

The Subject Device Shield System has the same modes of operation and logic as the previous Siemens compatible system (cleared predicate device, K222625). The majority of components remained unchanged and maintained their functionality and direction of use. The two systems have similar technological characteristics, with the subject device able to individually control the shield leaves and is compatible with the Siemens Artis, as opposed to the predicate. The design controls, verification and validation testing, and performance data demonstrate that the changes do not affect the safety and effectiveness of the system.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Under the company's design controls, verification and validation (V&V) were performed to ensure that design outputs meet design inputs, and that the device conforms to the defined user needs and intended use. The Shield System's V&V plan included robust testing to ensure the safety and performance of the system executed as part of the initial release of the system and included in the K222625 submission. To validate the proposed changes and to establish substantial equivalence to the predicate device (K222625), relevant tests from the previous submission were repeated in partial / full. All test protocols have been established for the evaluation of the cleared device (either been established for evaluation of the device or by consensus standards) and no new test methods were required for the validation of the proposed changes. The testing performed demonstrated substantial equivalence between the Predicate and Subject devices.