December 20, 2024

InkSpace Imaging, Inc.
% Taras Bouzakine
Director, Regulatory Affairs
Veranex, Inc.
5420 Wade Park Blvd, Suite 204
Raleigh, North Carolina 27607

Re: K243675
Trade/Device Name: InkSpace Imaging Small Body Array
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: November 27, 2024
Received: November 27, 2024

Dear Taras Bouzakine:

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.

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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
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.

Submission Number *(if known)*

K243675

Device Name

InkSpace Imaging Small Body Array

Indications for Use *(Describe)*

The InkSpace Imaging Small Body Array is a receive-only coil, used for obtaining diagnostic images of general human anatomy in adult and pediatric patients such as cardiac, spine, shoulder, elbow, knee, foot, and prostate in Siemens 1.5T magnetic resonance imaging systems. These images, when interpreted by a trained physician, yield information that may assist in diagnosis.

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 summary of the Special 510(k) premarket notification for the InkSpace Imaging Small Body Array is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92.

GENERAL INFORMATION [807.92(A)(1)]

Applicant:

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Date Prepared: December 18, 2024

DEVICE INFORMATION [807.92(A)(2)]

Classification:

Class II per 21 CFR§892.1000

Product Code:

MOS

Trade Name:

InkSpace Imaging Small Body Array

Generic/Common Name:

Coil, Magnetic Resonance, Specialty

PREDICATE DEVICE(S) [807.92(A)(3)]

InkSpace Imaging Small Body Array (K233444)

DEVICE DESCRIPTION [807.92(A)(4)]

The InkSpace Imaging Small Body Array is a phased array, receive-only coil intended to work with Siemens 1.5T MRI scanners for body MR imaging examinations. The coil is comprised of 24 total channels, with two individual flexible pads, each containing 12 individual elements. The elements are flexible to conform to patients' anatomies.

INDICATIONS FOR USE [807.92(A)(5)]

The InkSpace Imaging Small Body Array is a receive-only coil, used for obtaining diagnostic images of general human anatomy in adult and pediatric patients such as cardiac, spine, shoulder, elbow, knee, foot, and prostate in Siemens 1.5T magnetic resonance imaging systems. These images, when interpreted by a trained physician, yield information that may assist in diagnosis.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(A)(6)]

The technological characteristics of the modified InkSpace Imaging Small Body Array for 1.5T scanners are substantially equivalent to the predicate device, the InkSpace Imaging Small Body Array for 3.0T scanners (K233444). Table 1 lists the technological characteristics of the predicate and modified devices and provides rationale to support a determination of substantial equivalence. Any differences between the devices do not raise any new or different questions of safety or effectiveness.

Table 1: Summary of Technological Characteristics

Characteristics	Subject Device: InkSpace Imaging Small Body Array - 1.5T	Predicate Device: InkSpace Imaging Small Body Array - 3.0T (K233444)	Substantial Equivalence Rationale
Classification	Magnetic Resonance Diagnostic Device per 21 CFR§892.1000	Magnetic Resonance Diagnostic Device per 21 CFR§892.1000	N/A (Same).
Product Code	MOS (Coil, Magnetic Resonance, Specialty)	MOS (Coil, Magnetic Resonance, Specialty)	N/A (Same).
Intended Use	The InkSpace Imaging Small Body Array for Siemens 1.5T MRI systems is indicated for use as an alternative to a traditional MRI receive array. The conformal fit and blanket-like construction are designed to decrease anxiety and optimize convenience for both the patient and the technologist during the MRI scan. Use of the device during these procedures should be performed by appropriately trained MRI technologists, and interpretation of the images produced by these scans should be performed only by board certified radiologists.	The InkSpace Imaging Small Body Array for Siemens 3.0T MRI systems is indicated for use as an alternative to a traditional MRI receive array. The conformal fit and blanket-like construction are designed to decrease anxiety and optimize convenience for both the patient and the technologist during the MRI scan. Use of the device during these procedures should be performed by appropriately trained MRI technologists, and interpretation of the images produced by these scans should be performed only by board certified radiologists.	Intended use of the modified device maintains the same general purpose and function as the predicate device, differing only by target MRI system field strength (1.5T vs. 3.0T).
Indications for Use	The InkSpace Imaging Small Body Array is a receive-only coil, used for obtaining diagnostic images of general human anatomy in adult and pediatric patients such as cardiac, spine, shoulder, elbow, knee, foot, and prostate in Siemens 1.5T magnetic resonance imaging systems. These images, when interpreted by a trained physician, yield information that may assist in diagnosis.	The InkSpace Imaging Small Body Array is a receive-only coil, used for obtaining diagnostic images of general human anatomy in adult and pediatric patients such as cardiac, spine, shoulder, elbow, knee, foot, and prostate in Siemens 3.0T magnetic resonance imaging systems. These images, when interpreted by a trained physician, yield information that may assist in diagnosis.	Indications for Use of the modified device maintains the same general purpose and function as the predicate device, differing only by target MRI system field strength (1.5T vs. 3.0T).
Patient Anatomy and Population	Imaging of general human anatomy, such as cardiac, spine, shoulder, elbow, knee, foot, and prostate.	Imaging of general human anatomy, such as cardiac, spine, shoulder, elbow, knee, foot, and prostate.	N/A (Same).

Table 1: Summary of Technological Characteristics (cont.)

Characteristics	Subject Device: InkSpace Imaging Small Body Array - 1.5T	Predicate Device: InkSpace Imaging Small Body Array - 3.0T (K233444)	Substantial Equivalence Rationale
Comparison of Technological Characteristics	24 channel, receive-only phased array, designed for 1.5T MR systems (63.6 MHz, hydrogen). Device is reusable, non-sterile, and by prescription only. Device is made of soft, pliable materials, and is composed of two identical 12ch pads.	24 channel, receive-only phased array, designed for 3.0T MR systems (123.2 MHz, hydrogen). Device is reusable, non-sterile, and by prescription only. Device is made of soft, pliable materials, and is composed of two identical 12ch pads.	Different receive frequencies (63.6 MHz vs. 123.2 MHz) due to operation at 1.5T vs. 3.0T. This difference is fully verified.
Compatible MRI Systems	Siemens 1.5T MRI Systems	Siemens 3.0T MRI Systems	Different MR field strength, same OEM. This difference is fully verified.
Biocompatibility	ISO 10993 testing	ISO 10993 testing	N/A (Same).

SUBSTANTIAL EQUIVALENCE

The InkSpace Imaging Small Body Array for 1.5T scanners is substantially equivalent to the predicate device, the InkSpace Imaging Small Body Array for 3.0T scanners, with regard to function, intended use, and physical characteristics. There are no differences in the technological characteristics between the devices which would raise any different questions of safety or effectiveness. Thus, the InkSpace Imaging Small Body Array is substantially equivalent to the predicate device.

PERFORMANCE DATA [807.92(B)]

Performance testing was performed in accordance with the FDA Guidance Document entitled, "*Magnetic Resonance (MR) Receive-only Coil – Performance Criteria for Safety and Performance Based Pathway*," issued December 11, 2020.

Some of the nonclinical testing conducted on the InkSpace Imaging Small Body Array for 3.0T scanners (predicate device) is still applicable to the modified InkSpace Imaging Small Body Array for 1.5T scanners (subject of this submission).

Additional analysis was conducted based on the differences between 1.5T MR and 3.0T MR systems. These results and representative scan images listed below have been included as part of this submission.

[807.92(b)(1)] Nonclinical Testing Summary:

The nonclinical, bench tests, per the FDA Guidance Document entitled, "*Magnetic Resonance (MR) Receive-only Coil – Performance Criteria for Safety and Performance Based Pathway*," were performed on the InkSpace Imaging Small Body Array for 1.5T scanners:

- Image Signal to Noise (SNR)
- Image Uniformity
- Surface Heating
- Decoupling Circuit
- EMC – Immunity, Electrostatic Discharge
- General Electrical/Mechanical Safety
- Acquired Image Quality

In addition to the above listed nonclinical testing, a risk analysis was performed to validate that the following testing performed on the InkSpace Imaging Small Body Array for 3.0T scanners (predicate device) could be applied to the InkSpace Imaging Small Body Array for 1.5T scanners without retesting:

- Biocompatibility Testing (Cytotoxicity, Sensitization, Irritation)
- Usability Testing
- Transit Testing

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the InkSpace Imaging Small Body Array meet the

established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the InkSpace Imaging Small Body Array does not raise different questions of safety or effectiveness for MR imaging examinations with Siemens 1.5T MRI Systems when compared to the predicate device.

[807.92(b)(2)] Clinical Testing Summary:

Not applicable. Clinical testing was not required to demonstrate substantial equivalence of the modified InkSpace Imaging Small Body Array to the predicate device. Acquired image quality was analyzed based on sample clinical images. These images, as well as a review of their clinical quality by a board-certified radiologist, have been included as part of this submission.

CONCLUSIONS [807.92(B)(3)]

Based on the results from the nonclinical tests performed in support of the InkSpace Imaging Small Body Array, it is concluded that the modified device is safe, effective, and performs at least as safely and effectively as the legally marketed predicate device.

SUMMARY

The InkSpace Imaging Small Body Array is substantially equivalent to the predicate device.