



October 20, 2025

InkSpace Imaging, Inc.
% Valerie Defiesta-Ng
Executive Director, Regulatory Affairs
Veranex, Inc.
5420 Wade Park Blvd, Suite 204
Raleigh, North Carolina 27607

Re: K253182

Trade/Device Name: InkSpace Imaging Small Body Array (SBA12PH30x)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: September 26, 2025
Received: September 26, 2025

Dear Valerie Defiesta-Ng:

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,

NINGZHI LI -S Digitally signed
by NINGZHI LI -S

for

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

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.

K253182

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Please provide the device trade name(s).

?

InkSpace Imaging Small Body Array (SBA12PH30x)

Please provide your Indications for Use below.

?

The InkSpace Imaging Small Body Array is a receive-only coil, used for obtaining diagnostic images of general human anatomy, such as cardiac, hip, shoulder, liver, knee, and ankle in Philips 3.0T magnetic resonance imaging systems. These images, when interpreted by a trained physician, yield information that may assist in diagnosis.

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)

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510(k) #: K253182		510(k) Summary		Prepared on: 2025-09-26	
Contact Details		21 CFR 807.92(a)(1)			
Applicant Name		InkSpace Imaging, Inc.			
Applicant Address		5635 West Las Positas Blvd, Suite 403/404 Pleasanton CA 94588 United States			
Applicant Contact Telephone		925-425-7410			
Applicant Contact		Dr. Peter Fischer			
Applicant Contact Email		peter@inkspaceimaging.com			
Correspondent Name		Veranex, Inc.			
Correspondent Address		5420 Wade Park Blvd, Suite 204 Raleigh NC 27607 United States			
Correspondent Contact Telephone		408-505-7885			
Correspondent Contact		Ms. Valerie Defiesta-Ng			
Correspondent Contact Email		Valerie.defiesta-ng@veranex.com			
Device Name		21 CFR 807.92(a)(2)			
Device Trade Name		InkSpace Imaging Small Body Array (SBA12PH30x)			
Common Name		Magnetic resonance diagnostic device			
Classification Name		Coil, Magnetic Resonance, Specialty			
Regulation Number		892.1000			
Product Code(s)		MOS			
Legally Marketed Predicate Devices		21 CFR 807.92(a)(3)			
Predicate#	Predicate Trade Name (Primary Predicate is listed first)	Product Code			
K233444	InkSpace Imaging Small Body Array	MOS			
Device Description Summary		21 CFR 807.92(a)(4)			
<p>The InkSpace Imaging Small Body Array is a phased array, receive-only coil designed to work on Philips 3.0 Tesla (3.0T) MRI scanners. It consists of 12 elements which are optimized to be lightweight and flexible to easily conform to a patient's anatomy, providing high signal -to-noise ratio. The elements are enclosed in a soft padded pouch which can be wiped clean. The array is designed for proton imaging at 3.0 Tesla and has an optimal field of view of 27x25cm.</p>					
Intended Use/Indications for Use		21 CFR 807.92(a)(5)			
<p>The InkSpace Imaging Small Body Array is a receive-only coil, used for obtaining diagnostic images of general human anatomy, such as cardiac, hip, shoulder, liver, knee, and ankle in Philips 3.0T magnetic resonance imaging systems. These images, when interpreted by a trained physician, yield information that may assist in diagnosis.</p>					

Indications for Use Comparison	21 CFR 807.92(a)(5)
Indications for Use of the modified device maintain the same general purpose and function as the predicate device, differing only by compatible MR scanner type (Siemens vs. Philips).	
Technological Comparison	21 CFR 807.92(a)(6)
<p>The lnkSpace Imaging Small Body Array is substantially equivalent to the predicate device, the lnkSpace Imaging Small Body Array (K233444). The reason for this Special 510(k) submission is a modification to the target magnetic resonance imaging (MRI) system original equipment manufacturer (OEM) from Siemens to Philips. Philips MRI systems operate at 127.73MHz and can only support a single 12 channel pad (coil). The Device Description is, likewise, substantially equivalent to that submitted under K233444 for the lnkSpace Imaging Small Body Array, with only non-substantive modifications for clarity and updated photos, images, diagrams, and the like for a single 12 channel pad.</p>	
Non-Clinical and/or Clinical Tests Summary & Conclusions	21 CFR 807.92(b)
<p>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.</p> <p>Some of the nonclinical testing conducted on the predicate lnkSpace Imaging Small Body Array for 3.0T Siemens scanners (K233444) is still applicable to the modified lnkSpace Imaging Small Body Array for 3.0T Philips scanners (subject of this submission).</p> <p>Additional analysis was conducted based on the differences between 3.0T Philips MRI and 3.0T Siemens MRI systems.</p> <p>Nonclinical Testing Summary:</p> <p>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 lnkSpace Imaging Small Body Array for Philips 3.0T scanners:</p> <ul style="list-style-type: none"> - Image Signal to Noise (SNR) - Image Uniformity - Surface Heating - Decoupling Circuit - EMC - Immunity, Electrostatic Discharge - General Electrical/Mechanical Safety - Acquired Image Quality <p>In addition to the above nonclinical testing, the lnkSpace Imaging Small Body Array, having only one coil, also underwent the following testing:</p> <ul style="list-style-type: none"> - Transit Testing <p>In addition to the above nonclinical testing, a risk analysis was performed to validate that the following testing performed on the predicate lnkSpace Imaging Small Body Array for 3.0T Siemens scanners (K233444) could be applied to the lnkSpace Imaging Small Body Array for Philips 3.0T scanners without retesting:</p> <ul style="list-style-type: none"> - Biocompatibility Testing (Cytotoxicity, Sensitization, Irritation) - Usability 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 Philips 3.0T MRI Systems when compared to the predicate device.

Clinical Testing Summary:

Not applicable. Clinical testing was not required to demonstrate substantial equivalence of 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:

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 as safe and effective as the legally marketed predicate device. The InkSpace Imaging Small Body Array is substantially equivalent to the predicate device.