InkSpace Imaging, Inc.
% Taras Bouzakine
Director, Regulatory Affairs
Experien Group, LLC
224 Airport Parkway, Suite 250
SAN JOSE CA 95110

December 17, 2021

Re: K213397
Trade/Device Name: InkSpace Imaging Pediatric Body Array
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: October 15, 2021
Received: October 18, 2021

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213397

Device Name
InkSpace Imaging Pediatric Body Array

Indications for Use *(Describe)*
The InkSpace Imaging Pediatric Body Array is a receive-only coil, used for obtaining diagnostic images of pediatric cardiac and body in GE 3.0T 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 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Notification K213397

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

InkSpace Imaging, Inc.
5635 West Las Positas Blvd, Suite 403/404
Pleasanton, CA 94588
USA
Phone: 925-425-7410

Contact Person:

Taras Bouzakine
Director, Regulatory Affairs, Experien Group, LLC
Regulatory Consultant for InkSpace Imaging, Inc.
224 Airport Parkway, Suite 250
San Jose, CA 95110
USA

Date Prepared: October 15, 2021

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

InkSpace Imaging Pediatric Body Array

Generic/Common Name:

Coil, Magnetic Resonance, Specialty

Classification:

Class II per 21 CFR§892.1000

Product Code:

MOS

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

Pediatric Body-Cardiac Coil (K101949)

DEVICE DESCRIPTION [807.92(a)(4)]

The InkSpace Imaging Pediatric Body Array is a phased array, receive-only coil intended to work with GE 3.0T MRI scanners to provide optimal signal-to-noise ratio and uniformity for high resolution pediatric body MR imaging examinations. The size and layout of individual channels of the InkSpace Imaging Pediatric Body Array were designed specifically to fit the pediatric population for body imaging. The coil is comprised of 24 total channels, with two individual flexible pads, intended to be placed anterior and posterior to the patient, containing 12 individual elements. The elements are optimized to be flexible to conform to a pediatric patient's anatomy.

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

The InkSpace Imaging Pediatric Body Array is a receive-only coil, used for obtaining diagnostic images of pediatric cardiac and body in GE 3.0T 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 InkSpace Imaging Pediatric Body Array and its predicate, the Pediatric Body-Cardiac Coil (K101949), are classified as receive-only coils for 3.0 Tesla magnetic resonance imaging systems and are intended for use in obtaining diagnostic images of the body and cardiac regions of pediatric populations. Both devices detect hydrogen as the resonant nuclei and use phased array coil configurations to enhance overall signal to noise ratio. The proposed device and its predicate device have similar technological characteristics and employ the same operating principles. The primary technological difference between the two devices is that the predicate device utilizes an 8-element phased array RF structure, as opposed to the 24-elements of the proposed device. These minor differences in technological characteristics between the InkSpace Imaging Pediatric Body Array and the Pediatric Body-Cardiac Coil have been evaluated and determined to not raise any new or different questions of safety or effectiveness and thus is substantially equivalent to the predicate device.

SUBSTANTIAL EQUIVALENCE

A comparison table summarizing the specifications and features of the InkSpace Imaging Pediatric Body Array and the predicate device, the Pediatric Body-Cardiac Coil, is included in the Substantial Equivalence Table.

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.

All necessary nonclinical testing was conducted on the InkSpace Imaging Pediatric Body Array to support a determination of substantial equivalence to the predicate device.

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

The nonclinical testing included:

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

In addition to the above nonclinical testing, the InkSpace Imaging Pediatric Body Array also underwent the following testing:

- 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 the design of the InkSpace Imaging Pediatric 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 Pediatric Body Array does not raise new or different questions of safety or effectiveness for pediatric body MR imaging examinations when compared to the predicate device.

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

Not applicable. Clinical testing was not required to support substantial equivalence of the InkSpace Imaging Pediatric 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 Pediatric Body Array, it is concluded that the proposed device is safe, effective, and performs at least as safely and effectively as the legally marketed predicate device.

SUMMARY

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

Substantial Equivalence Table

Device Name	InkSpace Imaging Pediatric Body Array (Subject Device)	Pediatric Body-Cardiac Coil (Predicate)	Comparison
Classification	Magnetic Resonance Diagnostic Device per 21 CFR§892.1000	Magnetic Resonance Diagnostic Device per 21 CFR§892.1000	Same
Product Code	MOS (Coil, Magnetic Resonance, Specialty)	MOS (Coil, Magnetic Resonance, Specialty)	Same
Indications for Use	The InkSpace Imaging Pediatric Body Array is a receive-only coil, used for obtaining diagnostic images of pediatric cardiac and body in GE 3.0T magnetic resonance imaging systems. These images, when interpreted by a trained physician, yield information that may assist in diagnosis.	The Pediatric Body-Cardiac Coil is a receive-only coil, used for obtaining diagnostic images of pediatric cardiac and body in Philips Achieva 3.0T magnetic resonance imaging systems. These images when interpreted by a trained physician, yield information that may assist in diagnosis.	Similar. Only difference is the type of MRI system. The proposed device is used with the GE 3.0T MRI system while the predicate device is used with the Philips Achieva 3.0T MRI system.
Patient Anatomy and Population	Imaging of general body part regions including cardiac regions; designed for pediatric patients.	Imaging of general body part regions including cardiac regions; designed for pediatric patients.	Same
Comparison of Technological Characteristics	24 channel, receive-only phased array, designed for 3.0T MR systems (127.73 MHz, hydrogen). Device is reusable, non-sterile, and by prescription only. Device is made of soft, pliable materials, and is composed of an anterior and a posterior pad.	8 channel, receive-only phased array, designed for 3.0T MR systems (127.73 MHz, hydrogen). Device is reusable, non-sterile, and by prescription only. Device is made of rigid materials and is composed of a base plate coil and an anterior coil.	Similar. Differences do not raise any new or different questions of safety and effectiveness.
Compatible MRI Systems	GE 3.0T MRI Systems	Philips 3.0T MRI Systems	Similar. Differences do not raise any new or different questions of safety and effectiveness.
Biocompatibility	ISO 10993 testing	ISO 10993 testing	Same