FDA 510(k) Premarket Notification

K233444 InkSpace Imaging Small Body Array

CLEARED

Jan 8, 2024
81 days to decision

K233444 · Product code: **MOS** · Radiology
Source: https://www.510kdatabase.net/k233444/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Oct 19, 2023
Decision date	Jan 8, 2024
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Inkspace Imaging, Inc.**
Location	Pleasanton, CA, US
Contact	Peter Fischer
510(k) history	5 submissions · 5 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	**Veranex, Inc.**
Contact	Taras Bouzakine

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov