

K223487 InkSpace Imaging Body ArrayDec 8, 2022
17 days to decisionK223487 · Product code: **MOS** · Radiology
Source: <https://www.510kdatabase.net/k223487/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Nov 21, 2022
Decision date	Dec 8, 2022
Days to decision	17 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

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