

K253182 InkSpace Imaging Small Body Array (SBA12PH30x)Oct 20, 2025
24 days to decisionK253182 · Product code: **MOS** · Radiology
Source: <https://www.510kdatabase.net/k253182/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Sep 26, 2025
Decision date	Oct 20, 2025
Days to decision	24 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	Valerie Defiesta-Ng

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253182/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026