FDA 510(k) Premarket Notification

CLEARED

K213397 InkSpace Imaging Pediatric Body Array

Dec 17, 2021
60 days to decision

K213397 · Product code: **MOS** · Radiology
Source: https://www.510kdatabase.net/k213397/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Oct 18, 2021
Decision date	Dec 17, 2021
Days to decision	60 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	**Experien Group, LLC**
Contact	Taras Bouzakine

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