FDA 510(k) Premarket Notification

K213351 ds Head 32ch 3.0T

CLEARED

Oct 29, 2021
21 days to decision

K213351 · Product code: **MOS** · Radiology
Source: https://www.510kdatabase.net/k213351/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Oct 8, 2021
Decision date	Oct 29, 2021
Days to decision	21 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Invivo Corporation (Business Trade Name: Philips)**
Location	Florida, FL, US
Contact	Sarah Pleaugh
510(k) history	6 submissions · 6 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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