FDA 510(k) Premarket Notification

K222325 8ch Wrist Coil

CLEARED

Aug 31, 2022
29 days to decision

K222325 · Product code: **MOS** · Radiology
Source: https://www.510kdatabase.net/k222325/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Aug 2, 2022
Decision date	Aug 31, 2022
Days to decision	29 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	Connie Pascual
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