

**K213351 ds Head 32ch 3.0T**Oct 29, 2021  
21 days to decisionK213351 · Product code: **MOS** · Radiology  
Source: <https://www.510kdatabase.net/k213351/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

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

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