

K223378 3.0T 16ch AIR AAJan 3, 2023
57 days to decisionK223378 · Product code: **MOS** · Radiology
Source: <https://www.510kdatabase.net/k223378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Nov 7, 2022
Decision date	Jan 3, 2023
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ge Healthcare Coils (Usa Instruments, Inc.)
Location	Waukesha, WI, US
Contact	Lauren Ross
510(k) history	12 submissions · 12 cleared · 2009-2026

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