

K253738 3.0T AIR 32CH HNAJan 23, 2026
60 days to decisionK253738 · Product code: **MOS** · Radiology
Source: <https://www.510kdatabase.net/k253738/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Nov 24, 2025
Decision date	Jan 23, 2026
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253738/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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