

K143389 3.0T GEM RT Open ArrayMar 6, 2015
100 days to decisionK143389 · Product code: **MOS** · Radiology
Source: <https://www.510kdatabase.net/k143389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Nov 26, 2014
Decision date	Mar 6, 2015
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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