

K252179 GEM Flex Coil 16-L Array, 1.5T Receive OnlyFeb 10, 2026
214 days to decisionK252179 · Product code: **MOS** · Radiology
Source: <https://www.510kdatabase.net/k252179/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Jul 11, 2025
Decision date	Feb 10, 2026
Days to decision	214 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	GEM Flex Coil 16-M Array, 1.5T Receive Only; GEM Flex Coil 16-S Array, 1.5T Receive Only

APPLICANT

Company	Shenzhen RF Tech Co., Ltd.
Location	Shenzhen, CN
Contact	Gary Wang
510(k) history	12 submissions · 12 cleared · 2015-2026

REGULATORY CONSULTANT

Consulting firm	Bonnier QM Consulting Center
Contact	Gary Wang

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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