

K252876 GEM Flex Coil 16-L Array, 3.0T Receive OnlyApr 1, 2026
203 days to decisionK252876 · Product code: **MOS** · Radiology
Source: <https://www.510kdatabase.net/k252876/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Coil, Magnetic Resonance, Specialty (MOS) |
| Date received | Sep 10, 2025 |
| Decision date | Apr 1, 2026 |
| Days to decision | 203 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | GEM Flex Coil 16-M Array, 3.0T Receive Only; GEM Flex Coil 16-S Array, 3.0T Receive Only |

APPLICANT

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

REGULATORY CONSULTANT

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|-----------------|-------------------------------------|
| 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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