

K193140 Flex Body SPEEDERJan 3, 2020
51 days to decisionK193140 · Product code: **MOS** · Radiology
Source: <https://www.510kdatabase.net/k193140/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Nov 13, 2019
Decision date	Jan 3, 2020
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Quality Electrodynamics, LLC
Location	Mayfield Village, OH, US
Contact	Eric Yeh
510(k) history	21 submissions · 21 cleared · 2014-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193140/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026