FDA 510(k) Premarket Notification

K193140 Flex Body SPEEDER

CLEARED

Jan 3, 2020
51 days to decision

K193140 · 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