

**K190668 Encompass 15 Channel Head Coil, 3T**Sep 9, 2019  
178 days to decisionK190668 · Product code: **MOS** · Radiology  
Source: <https://www.510kdatabase.net/k190668/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Mar 15, 2019
Decision date	Sep 9, 2019
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Qfix</b>
Location	Avondale, PA, US
Contact	Alexandra Low Smythe
510(k) history	7 submissions · 7 cleared · 2015-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190668/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026