

**K191539 1.5T Endorectal Coil, 3.0T Endorectal Coil, ER Coil Support**Jan 31, 2020  
235 days to decisionK191539 · Product code: **MOS** · Radiology  
Source: <https://www.510kdatabase.net/k191539/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Jun 10, 2019
Decision date	Jan 31, 2020
Days to decision	235 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rapid Biomedical GmbH</b>
Location	Rimpar, DE
Contact	Christian Zimmermann
510(k) history	7 submissions · 7 cleared · 2008-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191539/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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