

K181948 1.5T 16Ch Diagnostic Breast Coil, 3.0T 16Ch Diagnostic Breast Coil

Nov 16, 2018
119 days to decision

K181948 · Product code: **MOS** · Radiology
Source: <https://www.510kdatabase.net/k181948/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Jul 20, 2018
Decision date	Nov 16, 2018
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k181948/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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