

**K220144 Breast BI Coil Set 0.55T**Apr 8, 2022  
79 days to decisionK220144 · Product code: **MOS** · Radiology  
Source: <https://www.510kdatabase.net/k220144/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Jan 19, 2022
Decision date	Apr 8, 2022
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Breast BI 7 MR Coil Set 1.5T; Breast BI 7 MR Coil Set 3T

**APPLICANT**

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Company	<b>Noras Mri Products GmbH</b>
Location	Hoechberg, DE
Contact	Manuel Noras
510(k) history	10 submissions · 10 cleared · 2008-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Kamm &amp; Associates</b>
Contact	Daniel Kamm

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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