

K191036 SyMRIJun 13, 2019
56 days to decisionK191036 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k191036/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Apr 18, 2019
Decision date	Jun 13, 2019
Days to decision	56 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Syntheticmr AB
Location	Linkoping, SE
Contact	Maria Almesaker
510(k) history	6 submissions · 6 cleared · 2017-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191036/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026