FDA 510(k) Premarket Notification

K211983 AMRA Profiler

CLEARED

Nov 24, 2021
152 days to decision

K211983 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k211983/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jun 25, 2021
Decision date	Nov 24, 2021
Days to decision	152 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Amra Medical AB**
Location	Linkoping, SE
Contact	Eric Converse
510(k) history	2 submissions · 2 cleared · 2018-2021

REGULATORY CONSULTANT

Consulting firm	**Arazy Group**
Contact	Raymond Kelly

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