FDA 510(k) Premarket Notification

K241069 iLoop Interventional Coil 0.55T

CLEARED

Jun 7, 2024
49 days to decision

K241069 · Product code: **MOS** · Radiology
Source: https://www.510kdatabase.net/k241069/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Apr 19, 2024
Decision date	Jun 7, 2024
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Kamm & Associates**
Contact	Daniel Kamm

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