FDA 510(k) Premarket Notification

K162931 Ingenia 1.5T CX and Ingenia 3.0T CX R5.3

CLEARED

Jan 6, 2017
79 days to decision

K162931 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k162931/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Oct 19, 2016
Decision date	Jan 6, 2017
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Medical Systems Nederland B.V.**
Location	Best, NL
Contact	Ruojuan Zhang
510(k) history	103 submissions · 102 cleared · 2005-2026