FDA 510(k) Premarket Notification

K232021 Smart Fit TorsoCardiac 1.5T and Smart Fit Shoulder 1.5T

CLEARED

Sep 1, 2023
56 days to decision

K232021 · Product code: **MOS** · Radiology
Source: https://www.510kdatabase.net/k232021/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Jul 7, 2023
Decision date	Sep 1, 2023
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Healthcare (Suzhou) Co., Ltd.**
Location	Suzhou Jiangsu, CN
Contact	Li Sherry
510(k) history	17 submissions · 17 cleared · 2014-2026