FDA 510(k) Premarket Notification

K241364 Hybrid Viewer (00859873006189)

CLEARED

Nov 8, 2024
178 days to decision

K241364 · Product code: **KPS** · Radiology
Source: https://www.510kdatabase.net/k241364/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	May 14, 2024
Decision date	Nov 8, 2024
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hermes Medical Solutions AB**
Location	Stockholm, SE
Contact	Hanne Grinaker
510(k) history	16 submissions · 16 cleared · 2012-2025