FDA 510(k) Premarket Notification

K241751 NeuroLF (Basic)

CLEARED

Jul 15, 2024
27 days to decision

K241751 · Product code: **KPS** · Radiology
Source: https://www.510kdatabase.net/k241751/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Jun 18, 2024
Decision date	Jul 15, 2024
Days to decision	27 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	NeuroLF (Pro); NeuroLF (Advanced); NeuroLF Seat

APPLICANT

Company	**Positrigo AG**
Location	Z?rich, CH
Contact	Jannis Fischer
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

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