FDA 510(k) Premarket Notification

K233908 cNeuro cDAT

CLEARED

Jul 1, 2024
202 days to decision

K233908 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k233908/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 12, 2023
Decision date	Jul 1, 2024
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Combinostics OY**
Location	Tampere, FI
Contact	Lennart Thurfjell
510(k) history	3 submissions · 3 cleared · 2018-2024

REGULATORY CONSULTANT

Consulting firm	**RQM+**
Contact	Erin Gontang

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