

K241819 CephNinja

Jan 23, 2025
213 days to decision

K241819 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k241819/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 24, 2024
Decision date	Jan 23, 2025
Days to decision	213 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cyncronus, LLC
Location	Bothel, WA, US
Contact	Rohit Madan
510(k) history	1 submissions · 1 cleared · 2025-2025

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](https://accessdata.fda.gov)
