FDA 510(k) Premarket Notification

K242215 Neurophet AQUA (V3.1)

CLEARED

Oct 25, 2024
88 days to decision

K242215 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k242215/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jul 29, 2024
Decision date	Oct 25, 2024
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neurophet., Inc.**
Location	Seoul, KR
Contact	Kim Byeolei
510(k) history	4 submissions · 4 cleared · 2022-2026

REGULATORY CONSULTANT

Consulting firm	**LK Consulting Group USA, Inc.**
Contact	Priscilla Chung

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