FDA 510(k) Premarket Notification

K220437 Neurophet AQUA

CLEARED

May 10, 2023
448 days to decision

K220437 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k220437/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Feb 16, 2022
Decision date	May 10, 2023
Days to decision	448 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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