

**K221405 Neurophet SCALE PET**Aug 5, 2022  
81 days to decisionK221405 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k221405/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 16, 2022
Decision date	Aug 5, 2022
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>LK Consulting Group USA, Inc.</b>
Contact	Priscilla Chung

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

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