

K213801 Veuron-Brain-pAb2Feb 4, 2022
60 days to decisionK213801 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k213801/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 6, 2021
Decision date	Feb 4, 2022
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Heuron Co., Ltd.
Location	Incheon, KR
Contact	Dong Hoon Shin
510(k) history	5 submissions · 5 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	Lighten Bridge, LLC
Contact	Edward Park

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

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