

K203142 Veuron-Brain-pAbJan 15, 2021
87 days to decisionK203142 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k203142/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Oct 20, 2020
Decision date	Jan 15, 2021
Days to decision	87 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

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