FDA 510(k) Premarket Notification

K213801 Veuron-Brain-pAb2

CLEARED

Feb 4, 2022
60 days to decision

K213801 · 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