FDA 510(k) Premarket Notification

K203142 Veuron-Brain-pAb

CLEARED

Jan 15, 2021
87 days to decision

K203142 · 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