FDA 510(k) Premarket Notification

K203279 Veuron-Brain-mN1

CLEARED

Jul 12, 2022
613 days to decision

K203279 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k203279/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 6, 2020
Decision date	Jul 12, 2022
Days to decision	613 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	**Hogan Lovells US LLP**
Contact	John J Smith

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