

K231398 VUNO Med-DeepBrainOct 4, 2023
142 days to decisionK231398 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k231398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	May 15, 2023
Decision date	Oct 4, 2023
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vuno, Inc.
Location	Seoul, KR
Contact	Jiwon Song
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

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

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