FDA 510(k) Premarket Notification

K233391 cCeLL - In vivo

CLEARED

Aug 21, 2024
324 days to decision

K233391 · Product code: **GWG** · Neurology
Source: https://www.510kdatabase.net/k233391/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Neurological (GWG)
Date received	Oct 2, 2023
Decision date	Aug 21, 2024
Days to decision	324 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**VPIX Medical, Inc.**
Location	Daejeon, KR
Contact	Kyungmin Hwang
510(k) history	2 submissions · 2 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	**MRC Global, LLC**
Contact	Dawn N. Norman, MS

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