

K243429 HJY VisualNext 3D Endoscopic Vision SystemMay 21, 2025
197 days to decisionK243429 · Product code: **GWG** · Neurology
Source: <https://www.510kdatabase.net/k243429/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Neurological (GWG)
Date received	Nov 5, 2024
Decision date	May 21, 2025
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hjy Smart Medical Device Co., Ltd.
Location	Taipei City, TW
Contact	John Chen
510(k) history	2 submissions · 2 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243429/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026