

K222735 HJY VisualNext Endoscopic Vision SystemJul 28, 2023
322 days to decisionK222735 · Product code: **GWG** · Neurology
Source: <https://www.510kdatabase.net/k222735/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Neurological (GWG)
Date received	Sep 9, 2022
Decision date	Jul 28, 2023
Days to decision	322 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 Jiannyuh Chen
510(k) history	2 submissions · 2 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222735/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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