FDA 510(k) Premarket Notification

K230125 Neuroblade System

CLEARED

Oct 13, 2023
269 days to decision

K230125 · Product code: **GWG** · Neurology
Source: https://www.510kdatabase.net/k230125/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Neurological (GWG)
Date received	Jan 17, 2023
Decision date	Oct 13, 2023
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Clearmind Biomedical**
Location	Taipei, TW
Contact	Vance Lin
510(k) history	3 submissions · 3 cleared · 2020-2023

REGULATORY CONSULTANT

Consulting firm	**Coombs Medical Device Consulting, Inc.**
Contact	Craig Coombs

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