

K200925 Clarus Peel-Away Introducer SheathMar 18, 2021
345 days to decisionK200925 · Product code: **GWG** · Neurology
Source: <https://www.510kdatabase.net/k200925/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Neurological (GWG)
Date received	Apr 7, 2020
Decision date	Mar 18, 2021
Days to decision	345 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Clarus Medical, LLC
Location	Minneapolis, MN, US
Contact	Mark F. Brown
510(k) history	9 submissions · 9 cleared · 2001-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200925/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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