FDA 510(k) Premarket Notification

K242304 RED

CLEARED

Dec 6, 2024
123 days to decision

K242304 · Product code: **KLA** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k242304/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Esophageal Motility, Anorectal Motility, And Tube (KLA)
Date received	Aug 5, 2024
Decision date	Dec 6, 2024
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neuraxis, Inc.**
Location	Carmel, IN, US
Contact	Thomas Carrico
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**MRC Global, LLC**
Contact	Dawn Norman

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

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Device record: https://www.510kdatabase.net/k242304/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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