FDA 510(k) Premarket Notification

K232618 Aurora Surgiscope System

CLEARED

Oct 27, 2023
59 days to decision

K232618 · Product code: **GWG** · Neurology
Source: https://www.510kdatabase.net/k232618/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Neurological (GWG)
Date received	Aug 29, 2023
Decision date	Oct 27, 2023
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Rebound Therapeutics Corporation**
Location	Irvine, CA, US
Contact	Timothy Connors
510(k) history	2 submissions · 2 cleared · 2019-2023