FDA 510(k) Premarket Notification

K201840 Aurora Surgiscope System (Surgiscope), Aurora Surgiscope System (Image Control Box)

CLEARED

Nov 4, 2020
125 days to decision

K201840 · Product code: **GWG** · Neurology
Source: https://www.510kdatabase.net/k201840/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Neurological (GWG)
Date received	Jul 2, 2020
Decision date	Nov 4, 2020
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Rebound Therapeutics**
Location	Irvine, CA, US
Contact	Naomi Gong
510(k) history	6 submissions · 6 cleared · 2018-2021