

K250752 AURORA® Surgiscope® System (ASX15/60)Apr 9, 2025
28 days to decisionK250752 · Product code: **GWG** · Neurology
Source: <https://www.510kdatabase.net/k250752/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscope, Neurological (GWG)
Date received	Mar 12, 2025
Decision date	Apr 9, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	AURORA® Surgiscope® System (ASX15/80)

APPLICANT

Company	Integra LifeSciences Corporation
Location	Planisboro, NJ, US
Contact	Rebecca Odulio
510(k) history	65 submissions · 65 cleared · 2004-2025

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