

K254133 ENTity USB Videoscope SystemMay 14, 2026
143 days to decisionK254133 · Product code: **EOB** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k254133/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nasopharyngoscope (flexible Or Rigid) (EOB)
Date received	Dec 22, 2025
Decision date	May 14, 2026
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Optim, LLC
Location	Sturbridge, MA, US
Contact	Sheldon Sillyman
510(k) history	4 submissions · 4 cleared · 2012-2026

REGULATORY CONSULTANT

Consulting firm	Delphi Medical Device Consulting, Inc.
Contact	Pamela Papineau

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

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