

K200609 ENTity WiFi Video Nasopharyngoscope SystemJan 13, 2021
310 days to decisionK200609 · Product code: **EOB** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k200609/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nasopharyngoscope (flexible Or Rigid) (EOB)
Date received	Mar 9, 2020
Decision date	Jan 13, 2021
Days to decision	310 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Optim, LLC
Location	Sturbridge, MA, US
Contact	Jenna Lipka
510(k) history	3 submissions · 3 cleared · 2012-2021

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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