

K232435 Rhinolaryngoscope systemApr 26, 2024
256 days to decisionK232435 · Product code: **EOB** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k232435/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nasopharyngoscope (flexible Or Rigid) (EOB)
Date received	Aug 14, 2023
Decision date	Apr 26, 2024
Days to decision	256 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen HugeMed Medical Technical Development Co., Ltd.
Location	Shenzhen, CN
Contact	Cathy Shi
510(k) history	7 submissions · 7 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Shenzhen Chonconn Medical Consulting Co., Ltd.
Contact	Yang Jie

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232435/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026