

K234096 MonoStereoSep 19, 2024
268 days to decisionK234096 · Product code: **EOB** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k234096/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nasopharyngoscope (flexible Or Rigid) (EOB)
Date received	Dec 26, 2023
Decision date	Sep 19, 2024
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Medicaltek Co., Ltd.
Location	Taichung City, TW
Contact	Shen Ching (James) Yeh
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Arazy Group Consultants, Inc.
Contact	Raymond Kelly

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/k234096/> 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 14, 2026