FDA 510(k) Premarket Notification

K234096 MonoStereo

CLEARED

Sep 19, 2024
268 days to decision

K234096 · Product code: **EOB** · Ear, Nose, Throat
Source: 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