

K230502 Ear Pressure Relief Device(Model:ER813B)Jun 9, 2023
105 days to decisionK230502 · Product code: **MJV** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k230502/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Inflation, Middle Ear (MJV)
Date received	Feb 24, 2023
Decision date	Jun 9, 2023
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ningbo Albert Novosino Co., Ltd.
Location	Ningbo, CN
Contact	Victor Zhou
510(k) history	2 submissions · 2 cleared · 2017-2023

REGULATORY CONSULTANT

Consulting firm	Shanghai CV Technology Co., Ltd.
Contact	Doris Dong

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/k230502/> 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 26, 2026