

K181838 Sinusway Dilation SystemDec 20, 2018
163 days to decisionK181838 · Product code: **LRC** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k181838/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ent Manual Surgical (LRC)
Date received	Jul 10, 2018
Decision date	Dec 20, 2018
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	3nt Medical , Ltd.
Location	Rosh Ha'ayin, IL
Contact	Ehud Bendory
510(k) history	4 submissions · 4 cleared · 2017-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181838/> 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 27, 2026