

K133921 PRECEPTIS TYMPANOSTOMY TUBE INSERTERAug 22, 2014
242 days to decisionK133921 · Product code: **ETD** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k133921/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tympanostomy (ETD)
Date received	Dec 23, 2013
Decision date	Aug 22, 2014
Days to decision	242 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Preceptis Medical
Location	Plymouth, MN, US
Contact	KEITH LELAND
510(k) history	3 submissions · 3 cleared · 2014-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133921/> 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 June 4, 2026