FDA 510(k) Premarket Notification

K133921 PRECEPTIS TYMPANOSTOMY TUBE INSERTER

CLEARED

Aug 22, 2014
242 days to decision

K133921 · 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