FDA 510(k) Premarket Notification

K081542 MODIFICATION TO ENTELLUS MEDICAL RS-SERIES SYSTEM

CLEARED

Jun 27, 2008
25 days to decision

K081542 · Product code: **LRC** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k081542/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Ent Manual Surgical (LRC)
Date received	Jun 2, 2008
Decision date	Jun 27, 2008
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Entellus Medical, Inc.**
Location	Maple Grove, MN, US
Contact	Sew-Wah Tay
510(k) history	27 submissions · 27 cleared · 2008-2022