FDA 510(k) Premarket Notification

K162192 BluePro

CLEARED

Dec 15, 2016
133 days to decision

K162192 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k162192/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Aug 4, 2016
Decision date	Dec 15, 2016
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bluesom**
Location	Orvault, FR
Contact	Erwan Floch
510(k) history	1 submissions · 1 cleared · 2016-2016