FDA 510(k) Premarket Notification

K132003 WINX SLEEP THERAPY SYSTEM

CLEARED

Jun 13, 2014
347 days to decision

K132003 · Product code: **OZR** · Anesthesiology
Source: https://www.510kdatabase.net/k132003/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intraoral Pressure Gradient Device (OZR)
Date received	Jul 1, 2013
Decision date	Jun 13, 2014
Days to decision	347 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Apnicure, Inc.**
Location	Redwood City, CA, US
Contact	CHRIS DANIEL
510(k) history	4 submissions · 4 cleared · 2012-2014