

K160239 TAP 3, TAP 1Aug 10, 2016
191 days to decisionK160239 · Product code: **PLC** · Dental
Source: <https://www.510kdatabase.net/k160239/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleep Appliances With Patient Monitoring (PLC)
Date received	Feb 1, 2016
Decision date	Aug 10, 2016
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Airway Management, Inc.
Location	Dallas, TX, US
Contact	Dale Siebenmorgen
510(k) history	6 submissions · 6 cleared · 2006-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160239/> 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 May 24, 2026