

**K181571 OASYS Oral/Nasal Airway System and OASYS Herbst
with Dentitrac Patient Monitor**Apr 19, 2019
309 days to decisionK181571 · Product code: **PLC** · Dental
Source: <https://www.510kdatabase.net/k181571/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleep Appliances With Patient Monitoring (PLC)
Date received	Jun 14, 2018
Decision date	Apr 19, 2019
Days to decision	309 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mark Abramson, D.D.S., Inc.
Location	Redwood City, CA, US
Contact	Mark Abramson
510(k) history	2 submissions · 2 cleared · 2003-2019

REGULATORY CONSULTANT

Consulting firm	Fishermed Consulting, LLC
Contact	Cheryl Fisher

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181571/>; 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 June 29, 2026