

K162816 SML-OSA2 AppliancesJul 27, 2017
294 days to decisionK162816 · Product code: **LQZ** · Dental
Source: <https://www.510kdatabase.net/k162816/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Jaw Repositioning (LQZ)
Date received	Oct 6, 2016
Decision date	Jul 27, 2017
Days to decision	294 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Selane Products, Inc.
Location	Bradenton, FL, US
Contact	JOHN CHRISTIAN
510(k) history	2 submissions · 2 cleared · 2013-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162816/> 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 1, 2026