

**K192412 SD500 Elite LubeFree High Speed Handpiece, SD500 Elite Lubricated High Speed Handpiece, SD500 Pro LubeFree High Speed Handpiece, Pro Lubricated High Speed Handpiece**Jan 6, 2020  
124 days to decisionK192412 · Product code: EFB · Dental  
Source: <https://www.510kdatabase.net/k192412/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	Sep 4, 2019
Decision date	Jan 6, 2020
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Dentalez, Inc.</b>
Location	Lancaster, PA, US
Contact	Robert Young
510(k) history	7 submissions · 7 cleared · 2007-2020

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192412/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 21, 2026