

**K200100 Abutment Design**Oct 7, 2020  
265 days to decisionK200100 · Product code: **PNP** · Dental  
Source: <https://www.510kdatabase.net/k200100/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dental Abutment Design Software For Dental Laboratory (PNP)
Date received	Jan 16, 2020
Decision date	Oct 7, 2020
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>3Shape A/S</b>
Location	Copenhagen, DK
Contact	Jenny Axel
510(k) history	8 submissions · 8 cleared · 2016-2020

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200100/> 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 28, 2026