

**K181266 Implantswiss Dental Implant System, Implantswiss  
Dental Abutment System**Nov 1, 2018  
171 days to decisionK181266 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k181266/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	May 14, 2018
Decision date	Nov 1, 2018
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Novodent SA</b>
Location	Yverdons-Les-Bains, CH
Contact	Cem Kocer
510(k) history	2 submissions · 2 cleared · 2018-2020

**REGULATORY CONSULTANT**

---

Consulting firm	<b>CardioMed Device Consultants, LLC</b>
Contact	H. Semih Oktay

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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181266/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026