

**K180184 Zeramex(R) XT Dental Implant System, NobelPearl
Dental Implant System**Nov 16, 2018
297 days to decisionK180184 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k180184/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jan 23, 2018
Decision date	Nov 16, 2018
Days to decision	297 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dentalpoint AG
Location	Dundas, CA
Contact	Anja Lieberherr
510(k) history	4 submissions · 4 cleared · 2014-2018

REGULATORY CONSULTANT

Consulting firm	Mapi USA, Inc.
Contact	Elizabeth Rose

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/k180184/>; 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 28, 2026