

**K181580 Cortex CAD/CAM Abutments**Jan 29, 2019  
228 days to decisionK181580 · Product code: **NHA** · Dental  
Source: <https://www.510kdatabase.net/k181580/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jun 15, 2018
Decision date	Jan 29, 2019
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Cortex Dental Implants Industries , Ltd.</b>
Location	Mizpe Aviv, M.P. Misgav, IL
Contact	Ronit Polack
510(k) history	4 submissions · 4 cleared · 2009-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Licensale, Inc.</b>
Contact	Raymond Kelly

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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