

K180609 Rodo SmilekeyMay 23, 2018
76 days to decisionK180609 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k180609/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Mar 8, 2018
Decision date	May 23, 2018
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rodo Medical, Inc.
Location	San Jose, CA, US
Contact	Michael Parsons
510(k) history	3 submissions · 3 cleared · 2016-2020

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Randy Prebula

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

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