

K220482 SherlockJun 21, 2022
123 days to decisionK220482 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k220482/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Feb 18, 2022
Decision date	Jun 21, 2022
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Open Implants, LLC
Location	Woburn, MA, US
Contact	Gregg Gellman
510(k) history	4 submissions · 4 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	Activi, LLC
Contact	Chris Brown

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

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