

K212664 SherlockNov 30, 2021
99 days to decisionK212664 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k212664/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Aug 23, 2021
Decision date	Nov 30, 2021
Days to decision	99 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	Aclivi, LLC
Contact	Chris Brown

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212664/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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