

K212394 Implant-One Multi-Unit AbutmentMar 23, 2023
598 days to decisionK212394 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k212394/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Aug 2, 2021
Decision date	Mar 23, 2023
Days to decision	598 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Implant Logistics, Inc.
Location	La Crosse, WI, US
Contact	Thomas Arendt
510(k) history	3 submissions · 3 cleared · 2018-2023

REGULATORY CONSULTANT

Consulting firm	PaxMed International, LLC
Contact	Floyd G. Larson

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/k212394/> 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 May 26, 2026