

**K191222 Inclusive Titanium Abutments compatible with:
Dentsply Implants Astra Tech Implant System EV**Aug 5, 2019
90 days to decisionK191222 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k191222/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	May 7, 2019
Decision date	Aug 5, 2019
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Prismatik Dentalcraft, Inc.
Location	Newport Beach, CA, US
Contact	Herbert Schoenhoefer
510(k) history	57 submissions · 57 cleared · 2010-2026

REGULATORY CONSULTANT

Consulting firm	PaxMed International, LLC
Contact	Kevin A. Thomas

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

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