FDA 510(k) Premarket Notification

K213391 High Retention Attachment System

CLEARED

Jan 11, 2022
88 days to decision

K213391 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k213391/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Oct 15, 2021
Decision date	Jan 11, 2022
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zest Anchors, LLC**
Location	Escondido, CA, US
Contact	Mark Stavro
Website	https://www.zestanchors.com
510(k) history	12 submissions · 12 cleared · 2012-2026

REGULATORY CONSULTANT

Consulting firm	**PaxMed International, LLC**
Contact	Melissa Burbage

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