FDA 510(k) Premarket Notification

K220612 PrimeLOC Attachment System

CLEARED

Jun 6, 2022
95 days to decision

K220612 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k220612/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Mar 3, 2022
Decision date	Jun 6, 2022
Days to decision	95 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Innovative Product Brands, Inc.**
Location	Highland, CA, US
Contact	Chris Gervais
510(k) history	2 submissions · 2 cleared · 2022-2023

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