FDA 510(k) Premarket Notification

CLEARED

K221019 Osteon Precision Milled Suprastructure

Jul 5, 2022
90 days to decision

K221019 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k221019/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Apr 6, 2022
Decision date	Jul 5, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Implant Solutions Pty Ltd (Aka Osteon Medical)**
Location	Mulgrave, AU
Contact	Andrea Del Ciotto
510(k) history	2 submissions · 2 cleared · 2022-2024

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