FDA 510(k) Premarket Notification

K243530 Dynamic TiBase

CLEARED

May 30, 2025
197 days to decision

K243530 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k243530/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Nov 14, 2024
Decision date	May 30, 2025
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Talladium Espa?a, SL**
Location	Lleida, ES
Contact	Xavier Soca Filella
510(k) history	7 submissions · 7 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	**PaxMed International, LLC**
Contact	Rebecca Kattan

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