FDA 510(k) Premarket Notification

K221966 Dynamic TiBase

CLEARED

Sep 15, 2022
72 days to decision

K221966 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k221966/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jul 5, 2022
Decision date	Sep 15, 2022
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Talladium Espana, SL**
Location	Lleida, ES
Contact	Xavier Soca Filella
510(k) history	3 submissions · 3 cleared · 2010-2022

REGULATORY CONSULTANT

Consulting firm	**PaxMed International, LLC**
Contact	Kevin Thomas

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