FDA 510(k) Premarket Notification

K231559 Multi-Unit DAS System

CLEARED

Nov 17, 2023
171 days to decision

K231559 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k231559/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	May 30, 2023
Decision date	Nov 17, 2023
Days to decision	171 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	Kevin A. Thomas

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