FDA 510(k) Premarket Notification

# K243732 Multi-Unit DAS System

**CLEARED**

Jan 29, 2026
421 days to decision

K243732 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k243732/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Abutment, Implant, Dental, Endosseous (NHA) |
| Date received | Dec 4, 2024 |
| Decision date | Jan 29, 2026 |
| Days to decision | 421 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

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k243732/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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