FDA 510(k) Premarket Notification

# K162021 3.0 Dynamic TiBase

**CLEARED**

May 4, 2018
652 days to decision

K162021 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k162021/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Abutment, Implant, Dental, Endosseous (NHA) |
| Date received | Jul 21, 2016 |
| Decision date | May 4, 2018 |
| Days to decision | 652 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Talladium Espana, SL** |
| Location | Lleida, ES |
| Contact | ESTEBAN XAM-MAR |
| 510(k) history | 3 submissions · 3 cleared · 2010-2022 |