

K151588 maxFit II Dental Implant SystemApr 25, 2016
319 days to decisionK151588 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k151588/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Jun 11, 2015 |
| Decision date | Apr 25, 2016 |
| Days to decision | 319 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Taiwan Implant Technology Company, Ltd. |
| Location | Kaohsiung, TW |
| Contact | Ching-Chieh Huang |
| 510(k) history | 1 submissions · 1 cleared · 2016-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151588/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 3, 2026