

K150388 Dental Implant SystemNov 12, 2015
267 days to decisionK150388 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k150388/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Feb 18, 2015 |
| Decision date | Nov 12, 2015 |
| Days to decision | 267 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Bio Concept Co., Ltd. |
| Location | Changzhou, CN |
| Contact | HUA CAO |
| 510(k) history | 3 submissions · 3 cleared · 2015-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150388/> 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 May 26, 2026