

K120089 BIOGENESIS IMPLANT SYSTEMMar 13, 2013
427 days to decisionK120089 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k120089/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Jan 11, 2012 |
| Decision date | Mar 13, 2013 |
| Days to decision | 427 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Biogenesis Co., Ltd. |
| Location | Anaheim, CA, US |
| Contact | Priscilla Chung |
| 510(k) history | 2 submissions · 2 cleared · 2013-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120089/> 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 4, 2026