

K153639 OneQ-SL s-Clean Implant SystemApr 8, 2016
109 days to decisionK153639 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k153639/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Dec 21, 2015 |
| Decision date | Apr 8, 2016 |
| Days to decision | 109 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Dentis Co., Ltd. |
| Location | Dalseo-Gu, KR |
| Contact | SUN CHUL SHIN |
| Website | https://www.dentis.co.kr |
| 510(k) history | 37 submissions · 37 cleared · 2008-2026 |

Dentis Co., Ltd. is a Dental device manufacturer based in Dalseo-Gu, South Korea. The company has received FDA 510(k) clearances from total submissions. All submissions focus on Dental devices, with a regulatory history spanning from 2008 to 2026. The company remains active, with recent clearances demonstrating ongoing product development and market engagement. Dentis specializes in dental implant systems, abutments, and associated clinical equipment. Recent cleared devices include implant fixtures, abutment components, scanning and healing systems, and dental chairs, ref...
