

K142313 OneQ-SL Implant SystemDec 10, 2015
478 days to decisionK142313 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k142313/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Aug 19, 2014
Decision date	Dec 10, 2015
Days to decision	478 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dentis Co., Ltd.
Location	Dalseo-Gu, KR
Contact	Jeong Seop Keun
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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142313/> 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