

K082843 MODIFICATON TO: DENTIS DENTAL IMPLANT SYSTEMJun 19, 2009
263 days to decisionK082843 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k082843/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 29, 2008
Decision date	Jun 19, 2009
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dentis Co., Ltd.
Location	Dalseo-Gu, KR
Contact	JUNG BAE BANG
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...