

**K083586 I-FIX SYSTEM**Apr 29, 2009  
146 days to decisionK083586 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k083586/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Dec 4, 2008
Decision date	Apr 29, 2009
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dentis Co., Ltd.</b>
Location	Dalseo-Gu, KR
Contact	JUNG BAE BANG
Website	<a href="https://www.dentis.co.kr">https://www.dentis.co.kr</a>
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...

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