

**K161244 s-Clean OneQ-SL Narrow Implant System**Dec 7, 2016  
218 days to decisionK161244 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k161244/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	May 3, 2016
Decision date	Dec 7, 2016
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dentis Co., Ltd.</b>
Location	Dalseo-Gu, KR
Contact	Sun Chul Shin
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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