

K180657 Resin for Temporary Crown & BridgeDec 7, 2018
269 days to decisionK180657 · Product code: **EBG** · Dental
Source: <https://www.510kdatabase.net/k180657/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Crown And Bridge, Temporary, Resin (EBG)
Date received	Mar 13, 2018
Decision date	Dec 7, 2018
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dentis Co., Ltd.
Location	Dalseo-Gu, KR
Contact	Dong-Hun Jang
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...

REGULATORY CONSULTANT

Consulting firm	Allura Medical Solution, Inc.
Contact	Soojung Moon

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k180657/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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