

K210080 Dentis s-Clean s-Line MiniJun 4, 2021
143 days to decisionK210080 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k210080/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Jan 12, 2021 |
| Decision date | Jun 4, 2021 |
| Days to decision | 143 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Dentis Co., Ltd. |
| Location | Dalseo-Gu, KR |
| Contact | Gyu Ri Kim |
| 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 | Withus Group, Inc. |
| Contact | April Lee |

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k210080/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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