

K190641 AR_N SLA Type Implant SystemFeb 21, 2020
345 days to decisionK190641 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k190641/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Mar 13, 2019
Decision date	Feb 21, 2020
Days to decision	345 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biotem Co., Ltd.
Location	Busan, KR
Contact	Hong Koo Yeo
510(k) history	6 submissions · 6 cleared · 2017-2023

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