

K190637 Fit & Brilliant Dental Implant SystemJun 19, 2020
465 days to decisionK190637 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k190637/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Mar 12, 2019
Decision date	Jun 19, 2020
Days to decision	465 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	F&B Technology Co., Ltd.
Location	Busan, KR
Contact	J H An
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Onbix Corporation
Contact	Ho Dong Yang

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190637/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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