

K190919 ST Internal Implant SystemFeb 27, 2020
324 days to decisionK190919 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k190919/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Apr 9, 2019
Decision date	Feb 27, 2020
Days to decision	324 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	T-Plus Implant Tech. Co., Ltd.
Location	New Taipei City, TW
Contact	Dana Cheng
510(k) history	4 submissions · 4 cleared · 2013-2020

REGULATORY CONSULTANT

Consulting firm	Puhsu Consulting , Ltd.
Contact	Yuhua Chen

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/k190919/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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