

**K102308 SIMPLELINE II MODEL SOFX483408R, SOFX483410R
TOTAL 44 MODELS**

Nov 22, 2010
98 days to decision

K102308 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k102308/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Aug 16, 2010
Decision date	Nov 22, 2010
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dentium Co., Ltd.
Location	Dunwoody, GA, US
Contact	EUNKYUNG SON
510(k) history	22 submissions · 22 cleared · 2004-2022

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k102308/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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