FDA 510(k) Premarket Notification

K052968 MODIFICATION TO: ORLUS MINI SCREW

CLEARED

Sep 8, 2006
322 days to decision

K052968 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k052968/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Oct 21, 2005
Decision date	Sep 8, 2006
Days to decision	322 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ortholution Co., Ltd.**
Location	Marietta, GA, US
Contact	CATHRYN CAMBRIA
510(k) history	3 submissions · 3 cleared · 2005-2008