FDA 510(k) Premarket Notification

K050568 ORLUS MINI SCREW

CLEARED

Jun 1, 2005
89 days to decision

K050568 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k050568/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Mar 4, 2005
Decision date	Jun 1, 2005
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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