FDA 510(k) Premarket Notification

K120414 OSSEOSPEED PLUS

CLEARED

Jul 31, 2012
172 days to decision

K120414 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k120414/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Feb 10, 2012
Decision date	Jul 31, 2012
Days to decision	172 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Astra Tech AB**
Location	San Diego, CA, US
Contact	LINDA K SCHULZ
510(k) history	10 submissions · 10 cleared · 2007-2013