FDA 510(k) Premarket Notification

K121131 BL, 04.1 MM RC, SLACTIVE 8MM, TIZR AND 10MM, 12, 14MM

CLEARED

Jun 6, 2012
54 days to decision

K121131 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k121131/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Apr 13, 2012
Decision date	Jun 6, 2012
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Straumann USA**
Location	Waltham, MA, US
Contact	ELAINE ALAN
510(k) history	41 submissions · 41 cleared · 1996-2016