

K121131 BL, 04.1 MM RC, SLACTIVE 8MM, TIZR AND 10MM, 12, 14MMJun 6, 2012
54 days to decisionK121131 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121131/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026