FDA 510(k) Premarket Notification

CLEARED

Nov 2, 2012
101 days to decision

K122192 NC TEMPORARY ABUTMENT, CAD-TEMP, PMMA RC TEMPORARY ABUTMENT, CAD-TEMP, PMMA RN TEMPORARY ABUTMENT, CAD-TEMP, PMMA WN TEM

K122192 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k122192/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jul 24, 2012
Decision date	Nov 2, 2012
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Straumann USA, LLC**
Location	Andover, MA, US
Contact	ELAINE ALAN
510(k) history	24 submissions · 24 cleared · 2012-2024

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k122192/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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