

K162311 Straumann PrefGelMar 7, 2017
201 days to decisionK162311 · Product code: **KJJ** · DentalSource: <https://www.510kdatabase.net/k162311/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cleanser, Root Canal (KJJ)
Date received	Aug 18, 2016
Decision date	Mar 7, 2017
Days to decision	201 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Institut Straumann AG
Location	Basel, CH
Contact	CHRISTOPHER KLACZYK
Website	https://www.straumann.com
510(k) history	88 submissions · 88 cleared · 1990-2026

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