

**K063812 STRAUMANN PREFGEL**Jan 12, 2007  
21 days to decisionK063812 · Product code: **KJJ** · DentalSource: <https://www.510kdatabase.net/k063812/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cleanser, Root Canal (KJJ)
Date received	Dec 22, 2006
Decision date	Jan 12, 2007
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Straumann USA</b>
Location	Waltham, MA, US
Contact	LISA M QUAGLIA
510(k) history	41 submissions · 41 cleared · 1996-2016

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k063812/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 17, 2026