

**K111809 SL TYPE ORTHODONTIC ANCHOR SCREWS, SPL  
TYPE ORTHODONTIC ANCHOR SCREWS**Sep 26, 2011  
91 days to decisionK111809 · Product code: **OAT** · Dental  
Source: <https://www.510kdatabase.net/k111809/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Orthodontic (OAT)
Date received	Jun 27, 2011
Decision date	Sep 26, 2011
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biomaterials Korea, Inc.</b>
Location	Littleton, CO, US
Contact	Kevin Walls
510(k) history	5 submissions · 5 cleared · 2007-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111809/>; 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 26, 2026