

**K222245 ACR Screw System**Aug 21, 2023  
391 days to decisionK222245 · Product code: **OAT** · Dental  
Source: <https://www.510kdatabase.net/k222245/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Orthodontic (OAT)
Date received	Jul 26, 2022
Decision date	Aug 21, 2023
Days to decision	391 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biomaterials Korea, Inc.</b>
Location	Littleton, CO, US
Contact	Young-yeop Kim
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/k222245/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026