

**K191041 Orthodontic Fixation Screw [Smart Anchor Miniscrew]**Aug 28, 2020  
497 days to decisionK191041 · Product code: **OAT** · Dental  
Source: <https://www.510kdatabase.net/k191041/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Orthodontic (OAT)
Date received	Apr 19, 2019
Decision date	Aug 28, 2020
Days to decision	497 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gni Co., Ltd.</b>
Location	Hwaseong, KR
Contact	Duk Soo Kim
510(k) history	3 submissions · 3 cleared · 2019-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191041/> 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 27, 2026