

**K201410 VENUS Bracket, ROSE Bracket**Mar 12, 2021  
288 days to decisionK201410 · Product code: **NJM** · Dental  
Source: <https://www.510kdatabase.net/k201410/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bracket, Ceramic, Orthodontic (NJM)
Date received	May 28, 2020
Decision date	Mar 12, 2021
Days to decision	288 days
Third-party review	No
Combination product	No
PCCP authorized	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

**REGULATORY CONSULTANT**

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Consulting firm	<b>E &amp; M</b>
Contact	Sang Hwa Myung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201410/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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