

K182672 ROSA BracketNov 15, 2019
415 days to decisionK182672 · Product code: **NJM** · Dental
Source: <https://www.510kdatabase.net/k182672/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bracket, Ceramic, Orthodontic (NJM)
Date received	Sep 26, 2018
Decision date	Nov 15, 2019
Days to decision	415 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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