

**K231635 A-Line Advanced**Jun 6, 2023  
1 days to decisionK231635 · Product code: **NJM** · Dental  
Source: <https://www.510kdatabase.net/k231635/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bracket, Ceramic, Orthodontic (NJM)
Date received	Jun 5, 2023
Decision date	Jun 6, 2023
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biocetec Co., Ltd.</b>
Location	Seoul, KR
Contact	Hee Sue Jin
510(k) history	4 submissions · 4 cleared · 2017-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Third Party Review Group, LLC</b>
Contact	Dave Yungvirt

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

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