

**K201038 Luce Ceramic Bracket**Oct 9, 2020  
172 days to decisionK201038 · Product code: **NJM** · Dental  
Source: <https://www.510kdatabase.net/k201038/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bracket, Ceramic, Orthodontic (NJM)
Date received	Apr 20, 2020
Decision date	Oct 9, 2020
Days to decision	172 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Luce Castle Co., Ltd.</b>
Location	Gyeonggi, KR
Contact	Kyung Joo Kim
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Provision Consulting Group, Inc.</b>
Contact	Joyce Bang-Kwon

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201038/> 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 June 28, 2026