

K190608 Mei Ceramic BracketNov 4, 2019
238 days to decisionK190608 · Product code: **NJM** · Dental
Source: <https://www.510kdatabase.net/k190608/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Bracket, Ceramic, Orthodontic (NJM) |
| Date received | Mar 11, 2019 |
| Decision date | Nov 4, 2019 |
| Days to decision | 238 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Orthosun Co., Ltd. |
| Location | Incheon, KR |
| Contact | Ju-Sung Lee |
| 510(k) history | 1 submissions · 1 cleared · 2019-2019 |

REGULATORY CONSULTANT

| | |
|-----------------|-------------------|
| Consulting firm | Plusglobal |
| Contact | Peter Chung |

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.netDevice record: <https://www.510kdatabase.net/k190608/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026