

K253461 Demi ProOct 14, 2025
7 days to decisionK253461 · Product code: **EBZ** · DentalSource: <https://www.510kdatabase.net/k253461/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Activator, Ultraviolet, For Polymerization (EBZ) |
| Date received | Oct 7, 2025 |
| Decision date | Oct 14, 2025 |
| Days to decision | 7 days |
| Third-party review | Yes |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Meta Systems Co., Ltd. |
| Location | Seoul, KR |
| Contact | Ray Jeon |
| 510(k) history | 4 submissions · 4 cleared · 2016-2025 |

REGULATORY CONSULTANT

| | |
|-----------------|--------------------------------------|
| Consulting firm | Third Party Review Group, LLC |
| Contact | Dave Yungvirt |

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/k253461/> 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 May 13, 2026