

K223395 Luna Dental Implant SystemFeb 3, 2023
87 days to decisionK223395 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k223395/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Abutment, Implant, Dental, Endosseous (NHA) |
| Date received | Nov 8, 2022 |
| Decision date | Feb 3, 2023 |
| Days to decision | 87 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Shinhung Mst Co., Ltd. |
| Location | Wonju-Si, KR |
| Contact | Sun Ho Lee |
| 510(k) history | 7 submissions · 7 cleared · 2013-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223395/> 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 27, 2026