

K100245 HS/HG PROSTHETIC SYSTEMAug 17, 2010
202 days to decisionK100245 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k100245/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Abutment, Implant, Dental, Endosseous (NHA) |
| Date received | Jan 27, 2010 |
| Decision date | Aug 17, 2010 |
| Days to decision | 202 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Osstem Implant Co., Ltd. |
| Location | Busan, KR |
| Contact | PATRICK LIM |
| Website | https://www.osstem.com |
| 510(k) history | 68 submissions · 68 cleared · 2006-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100245/>; 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 20, 2026