

K080594 MS SYSTEM (NARROW RIDGE)Sep 3, 2008
184 days to decisionK080594 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k080594/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Mar 3, 2008 |
| Decision date | Sep 3, 2008 |
| Days to decision | 184 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080594/>; 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 24, 2026