

K153043 Noris Medical MBI Dental Implant SystemApr 11, 2016
175 days to decisionK153043 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k153043/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Oct 19, 2015 |
| Decision date | Apr 11, 2016 |
| Days to decision | 175 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Noris Medical , Ltd. |
| Location | Nesher, IL |
| Contact | Simha Sibony |
| 510(k) history | 8 submissions · 8 cleared · 2014-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153043/> 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