

K160850 Nucleoss Tpure Implant SystemAug 4, 2017
494 days to decisionK160850 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k160850/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Mar 28, 2016 |
| Decision date | Aug 4, 2017 |
| Days to decision | 494 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Sanlilar Tibbi Cihazlar Med. Kim.San.Tic.Ltd.Sti |
| Location | Bolgesi Tekeli, TR |
| Contact | EZGI ERDEM |
| 510(k) history | 1 submissions · 1 cleared · 2017-2017 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160850/> 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 1, 2026