

K111287 ASTRA TECH IMPLANT SYSTEMSep 26, 2011
143 days to decisionK111287 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k111287/>**SUBMISSION DETAILS**

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|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | May 6, 2011 |
| Decision date | Sep 26, 2011 |
| Days to decision | 143 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Astra Tech AB |
| Location | San Diego, CA, US |
| Contact | LINDA K SCHULZ |
| 510(k) history | 10 submissions · 10 cleared · 2007-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111287/> 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 9, 2026