

K935638 NITINOL, NITIMay 18, 1994
176 days to decisionK935638 · Product code: **DZC** · Dental
Source: <https://www.510kdatabase.net/k935638/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Wire, Orthodontic (DZC) |
| Date received | Nov 23, 1993 |
| Decision date | May 18, 1994 |
| Days to decision | 176 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Highland Metals |
| Location | San Jose, CA, US |
| Contact | KENNETH HIGHLAND |
| 510(k) history | 7 submissions · 7 cleared · 1993-1994 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k935638/> 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 July 3, 2026