

K040043 NDX-40 ALLOYMar 3, 2004
51 days to decisionK040043 · Product code: **EJT** · DentalSource: <https://www.510kdatabase.net/k040043/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Alloy, Gold-based Noble Metal (EJT) |
| Date received | Jan 12, 2004 |
| Decision date | Mar 3, 2004 |
| Days to decision | 51 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Heraeus Kulzer, Inc. |
| Location | Elkhart, IN, US |
| Contact | CHERYL V ZIMMERMAN |
| 510(k) history | 145 submissions · 145 cleared · 1988-2009 |

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