

K905319 VARIOUSJan 15, 1991
48 days to decisionK905319 · Product code: **EJT** · DentalSource: <https://www.510kdatabase.net/k905319/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Alloy, Gold-based Noble Metal (EJT) |
| Date received | Nov 28, 1990 |
| Decision date | Jan 15, 1991 |
| Days to decision | 48 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Ivoclar North America, Inc. |
| Location | Amherst, NY, US |
| Contact | GARY L SEVERANCE |
| 510(k) history | 131 submissions · 131 cleared · 1989-2001 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k905319/>; 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 2, 2026