

K913100 PALFIQUE INLAYOct 2, 1991
82 days to decisionK913100 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k913100/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Material, Tooth Shade, Resin (EBF) |
| Date received | Jul 12, 1991 |
| Decision date | Oct 2, 1991 |
| Days to decision | 82 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Tokuyama America, Inc. |
| Location | Washington, DC, US |
| Contact | EMALEE G MURPHY |
| 510(k) history | 22 submissions · 22 cleared · 1990-2002 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k913100/> 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