

**K971284 OPALDAM**Jun 3, 1997  
57 days to decisionK971284 · Product code: **EIG** · DentalSource: <https://www.510kdatabase.net/k971284/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Retractor, All Types (EIG)
Date received	Apr 7, 1997
Decision date	Jun 3, 1997
Days to decision	57 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Ultradent Products, Inc.</b>
Location	Salt Lake City, UT, US
Contact	CHESTER MCCOY
Website	<a href="https://www.ultradent.com">https://www.ultradent.com</a>
510(k) history	103 submissions · 103 cleared · 1992-2026

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971284/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026