

**K012174 ERIS LAYERING MATERIALS**Aug 27, 2001  
46 days to decisionK012174 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k012174/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Jul 12, 2001
Decision date	Aug 27, 2001
Days to decision	46 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Ivoclar North America, Inc.</b>
Location	Amherst, NY, US
Contact	DONNA M HARTNETT
510(k) history	131 submissions · 131 cleared · 1989-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012174/> 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 July 2, 2026