

**K120011 HEISENBERG EFFECT SHADES**Jan 13, 2012  
10 days to decisionK120011 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k120011/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Jan 3, 2012
Decision date	Jan 13, 2012
Days to decision	10 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>3M Espe AG</b>
Location	Bavaria D-82228 Seefeld, DE
Contact	DESI W SOEGIARTO
510(k) history	6 submissions · 6 cleared · 2011-2014

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120011/> 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 6, 2026