

**K001326 NATURAL-IRIS PRE-PIGMENTED CORNEAL BUTTON**Jun 13, 2000  
48 days to decisionK001326 · Product code: **NCK** · Ophthalmic  
Source: <https://www.510kdatabase.net/k001326/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Button, Iris, Eye, Artificial (NCK)
Date received	Apr 26, 2000
Decision date	Jun 13, 2000
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ocular Concepts, LLC</b>
Location	Portland, OR, US
Contact	KEVIN SCHOU
510(k) history	1 submissions · 1 cleared · 2000-2000

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001326/> 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 29, 2026