

**K150594 Biodesign Otologic Repair Graft**Sep 16, 2015  
191 days to decisionK150594 · Product code: **KHJ** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k150594/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Ent Synthetic-polyamide (mesh Or Foil Material) (KHJ)
Date received	Mar 9, 2015
Decision date	Sep 16, 2015
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook Biotech Incorporated</b>
Location	West Lafayette, IN, US
Contact	PERRY W. GUINN
510(k) history	4 submissions · 4 cleared · 2013-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150594/> 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 3, 2026