

**K161000 Biodesign Otologic Repair Graft**May 11, 2016  
30 days to decisionK161000 · Product code: **KHJ** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k161000/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Polymer, Ent Synthetic-polyamide (mesh Or Foil Material) (KHJ)
Date received	Apr 11, 2016
Decision date	May 11, 2016
Days to decision	30 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	16 submissions · 16 cleared · 2013-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161000/> 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 May 26, 2026