

K121360 BIODESIGN ENT REPAIR GRAFTFeb 27, 2013
296 days to decisionK121360 · Product code: **KHJ** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k121360/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Ent Synthetic-polyamide (mesh Or Foil Material) (KHJ)
Date received	May 7, 2012
Decision date	Feb 27, 2013
Days to decision	296 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Biotech Incorporated
Location	West Lafayette, IN, US
Contact	MARY A FADERAN, PH.D., RAC
510(k) history	4 submissions · 4 cleared · 2013-2015

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