

K232646 Biodesign Otologic Butterfly Graft (ENT-OTO-BFLY-0.4-0.6)May 24, 2024
268 days to decisionK232646 · Product code: **KHJ** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k232646/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Ent Synthetic-polyamide (mesh Or Foil Material) (KHJ)
Date received	Aug 30, 2023
Decision date	May 24, 2024
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Biodesign Otologic Butterfly Graft (ENT-OTO-BFLY-0.6-0.9)

APPLICANT

Company	Cook Biotech Incorporated
Location	West Lafayette, IN, US
Contact	Christopher Lotzow
510(k) history	16 submissions · 16 cleared · 2013-2024

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