

K172389 ePTFE-Coated Auricular ImplantJul 18, 2018
344 days to decisionK172389 · Product code: **FZD** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k172389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Ear, Internal (FZD)
Date received	Aug 8, 2017
Decision date	Jul 18, 2018
Days to decision	344 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Implantech Associates, Inc.
Location	Washington, DC, US
Contact	Craig Arthur
510(k) history	41 submissions · 40 cleared · 1989-2020

REGULATORY CONSULTANT

Consulting firm	Acknowledge Regulatory Strategies, LLC
Contact	Allison Komiyama

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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