

K200610 Customized Contour ImplantDec 23, 2020
289 days to decisionK200610 · Product code: **FWP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k200610/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Chin, Internal (FWP)
Date received	Mar 9, 2020
Decision date	Dec 23, 2020
Days to decision	289 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	Pierre Bounaud

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

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