

**K191130 Customized Contour Implant**Aug 23, 2019  
116 days to decisionK191130 · Product code: **FWP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191130/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Chin, Internal (FWP)
Date received	Apr 29, 2019
Decision date	Aug 23, 2019
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Acknowledge Regulatory Strategies</b>
Contact	Pierre Bounaud

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191130/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 20, 2026