

**K230037 BACK 3**Jul 19, 2023  
194 days to decisionK230037 · Product code: **PBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230037/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Jan 6, 2023
Decision date	Jul 19, 2023
Days to decision	194 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Swims America Corp</b>
Location	White Plains, NY, US
Contact	Matthieu Commeau
510(k) history	4 submissions · 4 cleared · 2022-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230037/> 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 May 26, 2026