

K214090 Back 3 COLORNov 1, 2022
308 days to decisionK214090 · Product code: **PBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k214090/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Dec 28, 2021
Decision date	Nov 1, 2022
Days to decision	308 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Emergo by UL
Contact	Matthieu Commeau

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k214090/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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