

K220014 RSHOCKMar 1, 2023
420 days to decisionK220014 · Product code: **PBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220014/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Jan 5, 2022
Decision date	Mar 1, 2023
Days to decision	420 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/k220014/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026