

**K213256 ThermoTK**May 25, 2023  
602 days to decisionK213256 · Product code: **PBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213256/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Sep 30, 2021
Decision date	May 25, 2023
Days to decision	602 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zimmer Medizinsysteme GmbH</b>
Location	Neu-Ulm, DE
Contact	Ute Hauss
510(k) history	13 submissions · 13 cleared · 2016-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213256/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026