FDA 510(k) Premarket Notification

K240178 RFG-01

CLEARED

Jul 15, 2024
174 days to decision

K240178 · Product code: **PBX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k240178/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Jan 23, 2024
Decision date	Jul 15, 2024
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer Medizinsysteme GmbH**
Location	Neu-Ulm, DE
Contact	Ute Killet
510(k) history	13 submissions · 13 cleared · 2016-2026

REGULATORY CONSULTANT

Consulting firm	**Qara Consulting**
Contact	Scott Blood

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k240178/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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