

K250047 bite away twoSep 12, 2025
245 days to decision

K250047 · Product code: IRT · Physical Medicine

Source: <https://www.510kdatabase.net/k250047/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pad, Heating, Powered (IRT)
Date received	Jan 10, 2025
Decision date	Sep 12, 2025
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	mibeTec GmbH
Location	Brehna, DE
Contact	Oliver Grunert
510(k) history	2 submissions · 2 cleared · 2022-2025

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