

**K220514 bite away neo**Jun 23, 2022  
121 days to decisionK220514 · Product code: IRT · Physical Medicine  
Source: <https://www.510kdatabase.net/k220514/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pad, Heating, Powered (IRT)
Date received	Feb 22, 2022
Decision date	Jun 23, 2022
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>QSR Consulting</b>
Contact	Kenneth Kleinhenz

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220514/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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