

**K241066 BB-613-BPM**Jan 14, 2025  
271 days to decisionK241066 · Product code: **DXN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k241066/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Apr 18, 2024
Decision date	Jan 14, 2025
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biobeat Technologies , Ltd.</b>
Location	Petah Tikvah, IL
Contact	Johanan May
510(k) history	4 submissions · 4 cleared · 2019-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	John Smith

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/k241066/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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