FDA 510(k) Premarket Notification

K241066 BB-613-BPM

CLEARED

Jan 14, 2025
271 days to decision

K241066 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k241066/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	John Smith

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