FDA 510(k) Premarket Notification

CLEARED

K212153 Biobeat Platform, BB-613WP Patch

Mar 25, 2022
259 days to decision

K212153 · Product code: **DQA** · Cardiovascular
Source: https://www.510kdatabase.net/k212153/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Jul 9, 2021
Decision date	Mar 25, 2022
Days to decision	259 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 J. Smith

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