

K222010 Biobeat Platform-2 and BB-613WP PatchDec 30, 2022
176 days to decisionK222010 · Product code: **DQA** · Cardiovascular
Source: <https://www.510kdatabase.net/k222010/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Jul 7, 2022
Decision date	Dec 30, 2022
Days to decision	176 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

CLINICAL EVIDENCE - NCT04955184**Comparing Cardiac Output Measurements Using a Wearable, Wireless, Non-invasive PPG-Based Device to a Swan Ganz Catheter**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	100 patients (actual)
Study sites	1 site
Condition studied	Cardiac Output, Low; Cardiac Output, High; Congestive Heart Failure
Study type	Observational
Completion date	Jun 25, 2022
Sponsor	Biobeat Technologies Ltd. (Industry)

Primary outcome

Comparison of cardiac output obtained by a non-invasive device to the invasive method

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04955184