

K181006 BB-613 Watch OximeterSep 21, 2018
158 days to decisionK181006 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k181006/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Apr 16, 2018
Decision date	Sep 21, 2018
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Beat Technologies , Ltd.
Location	Petach Tikvah, IL
Contact	Johanan May
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Yarmela Pavlovic

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

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