

K182030 Faros MobileNov 8, 2018
101 days to decisionK182030 · Product code: **MLO** · Cardiovascular
Source: <https://www.510kdatabase.net/k182030/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO)
Date received	Jul 30, 2018
Decision date	Nov 8, 2018
Days to decision	101 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bittium Biosignals , Ltd.
Location	Kuopio, FI
Contact	Taneli Vaaraniemi
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182030/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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