

K163462 AQT90 FLEX Myo Test Kit, AQT90 FLEX CKMB Test Kit, AQT90 FLEXSep 21, 2017
286 days to decisionK163462 · Product code: JHX · Chemistry
Source: <https://www.510kdatabase.net/k163462/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorometric Method, Cpk Or Isoenzymes (JHX)
Date received	Dec 9, 2016
Decision date	Sep 21, 2017
Days to decision	286 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Radiometer Medical Aps
Location	Bronshoj, DK
Contact	Per Pape Thomsen
510(k) history	28 submissions · 28 cleared · 2004-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163462/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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