

K162117 NIRO-200NX DPOct 25, 2016
88 days to decisionK162117 · Product code: **MUD** · Cardiovascular
Source: <https://www.510kdatabase.net/k162117/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	Jul 29, 2016
Decision date	Oct 25, 2016
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hamamatsu Photonics K.K.
Location	Bridgewater, NJ, US
Contact	Susumu Suzuki
510(k) history	8 submissions · 8 cleared · 1989-2023

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