

K191147 OC-Auto SENSOR io iFOB TestJan 2, 2020
247 days to decisionK191147 · Product code: **OOX** · Hematology
Source: <https://www.510kdatabase.net/k191147/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Occult Blood Analyzer (OOX)
Date received	Apr 30, 2019
Decision date	Jan 2, 2020
Days to decision	247 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Eiken Chemical Co., Ltd.
Location	Taito-Ku, JP
Contact	Tadashi Yasuda
510(k) history	2 submissions · 2 cleared · 2015-2020

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