

K143325 OC-Light S FITAug 20, 2015
273 days to decisionK143325 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k143325/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Nov 20, 2014
Decision date	Aug 20, 2015
Days to decision	273 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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