

K223690 iFlash-HCGDec 11, 2023
367 days to decisionK223690 · Product code: **DHA** · Chemistry
Source: <https://www.510kdatabase.net/k223690/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Dec 9, 2022
Decision date	Dec 11, 2023
Days to decision	367 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Chemiluminescence Immunoassay Analyzer (Model: iFlash 3000-C)

APPLICANT

Company	Shenzhen Yhlo Biotech Co., Ltd.
Location	Shenzhen, CN
Contact	Ying Dai
510(k) history	1 submissions · 1 cleared · 2023-2023

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