

K163418 Diazyme DZ-Lite Total beta-hCG Test SystemAug 18, 2017
255 days to decisionK163418 · Product code: **DHA** · Chemistry
Source: <https://www.510kdatabase.net/k163418/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Dec 6, 2016
Decision date	Aug 18, 2017
Days to decision	255 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Diazyme Laboratories
Location	Irvine, CA, US
Contact	Abhijit Datta
510(k) history	41 submissions · 41 cleared · 2003-2018

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