FDA 510(k) Premarket Notification

CLEARED

K212221 Diazyme DZ-Lite iFlash Total beta-hCG Assay, Diazyme DZ-Lite iFlash 1800 Chemiluminescence Immunoassay Analyzer

Dec 13, 2021
150 days to decision

K212221 · Product code: **DHA** · Chemistry
Source: https://www.510kdatabase.net/k212221/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Jul 16, 2021
Decision date	Dec 13, 2021
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Diazyme Laboratories, Inc.**
Location	Poway, CA, US
Contact	Chao Dou
Website	https://www.diazyme.com/
510(k) history	10 submissions · 10 cleared · 2018-2026

Diazyme Laboratories, Inc. develops innovative clinical diagnostic reagents using proprietary enzyme and immunoassay technologies. Founded in 2000, the company specializes in diagnostic tests for cardiovascular disease, cancer, liver disease, renal disease, diabetes, sepsis, inflammatory disease, vitamins, and electrolytes. Diazyme operates a cGMP and ISO 13485 certified manufacturing facility in Poway, California, with additional operations in Europe and Shanghai. The company has received FDA 510(k) clearances from total submissions since 2018. Diazyme's cleared devices ...