FDA 510(k) Premarket Notification

K131037 LIAISON XL HCG

CLEARED

Sep 6, 2013
144 days to decision

K131037 · Product code: **DHA** · Chemistry
Source: https://www.510kdatabase.net/k131037/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Apr 15, 2013
Decision date	Sep 6, 2013
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**DiaSorin, Inc.**
Location	Ellicott City, MD, US
Contact	Mari Meyer
510(k) history	70 submissions · 69 cleared · 1998-2025