FDA 510(k) Premarket Notification

K102175 RAPIDVUE HCG TEST

CLEARED

Aug 25, 2010
23 days to decision

K102175 · Product code: **JHI** · Chemistry
Source: https://www.510kdatabase.net/k102175/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Aug 2, 2010
Decision date	Aug 25, 2010
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Quidel Corporation**
Location	San Diego, CA, US
Contact	Michelle Bodien
510(k) history	37 submissions · 35 cleared · 2010-2024