FDA 510(k) Premarket Notification

CLEARED

K062840 TRIAGE PROTEIN C CONTROLS AND CALIBRATION VERIFICATION CONTROLS

Mar 1, 2007
160 days to decision

K062840 · Product code: **GGN** · Hematology
Source: https://www.510kdatabase.net/k062840/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Sep 22, 2006
Decision date	Mar 1, 2007
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biosite Incorporated**
Location	San Diego, CA, US
Contact	FIL V BUENVIAJE
510(k) history	46 submissions · 45 cleared · 1990-2010