FDA 510(k) Premarket Notification

K082030 DIMENSION VISTA CSAE CALIBRATOR, MODEL KC440

CLEARED

Aug 22, 2008
36 days to decision

K082030 · Product code: **DLJ** · Toxicology
Source: https://www.510kdatabase.net/k082030/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Specific (DLJ)
Date received	Jul 17, 2008
Decision date	Aug 22, 2008
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Healthcare Diagnostics, Inc.**
Location	New York, NY, US
Contact	YUK-TING LEWIS
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026