FDA 510(k) Premarket Notification

K123996 RADIAL-CUF NON-INVASIVE BLOOD PRESSURE CUFF

CLEARED

Apr 9, 2013
104 days to decision

K123996 · Product code: **DXQ** · Cardiovascular
Source: https://www.510kdatabase.net/k123996/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood Pressure Cuff (DXQ)
Date received	Dec 26, 2012
Decision date	Apr 9, 2013
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Medical Systems Information Technologies, Inc.**
Location	Milwaukee, WI, US
Contact	MARY CARTER
510(k) history	31 submissions · 31 cleared · 2010-2026