FDA 510(k) Premarket Notification

K143332 Fast Sphyg by Koven

CLEARED

Apr 14, 2015
145 days to decision

K143332 · Product code: **DXQ** · Cardiovascular
Source: https://www.510kdatabase.net/k143332/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood Pressure Cuff (DXQ)
Date received	Nov 20, 2014
Decision date	Apr 14, 2015
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Koven Technology, Inc.**
Location	St. Louis, MO, US
Contact	HEATHER BELL
510(k) history	18 submissions · 18 cleared · 1994-2021