FDA 510(k) Premarket Notification

K093802 ULTRAVIEW DM3 MONITOR

CLEARED

Apr 9, 2010
119 days to decision

K093802 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k093802/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Dec 11, 2009
Decision date	Apr 9, 2010
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zoe Medical, Inc.**
Location	Topsfield, MA, US
Contact	JIM CHICKERING
510(k) history	5 submissions · 5 cleared · 2001-2021