

K093802 ULTRAVIEW DM3 MONITORApr 9, 2010
119 days to decisionK093802 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k093802/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026