

**K103058 MULTIFUNCTION KEITO**Nov 10, 2011  
392 days to decisionK103058 · Product code: **DXN** · CardiovascularSource: <https://www.510kdatabase.net/k103058/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Oct 14, 2010
Decision date	Nov 10, 2011
Days to decision	392 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aguiflai Iberica S.L.</b>
Location	Vilassar De Mar (Barcelona), ES
Contact	XAVIER CASALS
510(k) history	1 submissions · 1 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103058/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 18, 2026