

K113821 TRANSONIC COSTATUS CARDIAC OUTPUT SYSTEMSep 7, 2012
255 days to decisionK113821 · Product code: **DXG** · Cardiovascular
Source: <https://www.510kdatabase.net/k113821/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Dec 27, 2011
Decision date	Sep 7, 2012
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Transonic Systems, Inc.
Location	Ithaca, NY, US
Contact	NAVEEN THURAMALLA
510(k) history	16 submissions · 16 cleared · 1988-2015

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