

**K083301 X-COATED TERUMO AND SARNS DUAL STAGE  
VENOUS RETURN CATHETERS, SARNS MALLEABLE VENOUS  
AND DUAL STAGE RETURN CATHETERS**Dec 18, 2008  
38 days to decisionK083301 · Product code: **DWF** · Cardiovascular  
Source: <https://www.510kdatabase.net/k083301/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Nov 10, 2008
Decision date	Dec 18, 2008
Days to decision	38 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Terumo Cardiovascular Systems Corp.</b>
Location	Elkton, MD, US
Contact	JUNKO KUROSAWA
510(k) history	43 submissions · 43 cleared · 2000-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083301/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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