

**K043453 STERILEMED REPROCESSED IVUS IMAGING CATHETER**

Mar 1, 2005  
76 days to decision

K043453 · Product code: **OWQ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k043453/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Dec 15, 2004
Decision date	Mar 1, 2005
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sterilmed, Inc.</b>
Location	Plymouth, MN, US
Contact	BRUCE LESTER
510(k) history	64 submissions · 64 cleared · 2001-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k043453/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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