

K012537 REPROCESSED IMAGING CATHETERSOct 11, 2002
430 days to decisionK012537 · Product code: **OWQ** · CardiovascularSource: <https://www.510kdatabase.net/k012537/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Aug 7, 2001
Decision date	Oct 11, 2002
Days to decision	430 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sterilmed, Inc.
Location	Plymouth, MN, US
Contact	PATRICK FLEISCHHACKER
510(k) history	64 submissions · 64 cleared · 2001-2024

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