

K161700 SoundStar eco 8F 3D Diagnostic eco Ultrasound Catheters, SoundStar eco 8F G 3D Diagnostic eco Ultrasound Catheters

Nov 21, 2016
154 days to decision

K161700 · Product code: **OWQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k161700/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Jun 20, 2016
Decision date	Nov 21, 2016
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k161700/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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