

**K234064 Medline ReNewal Reprocessed Siemens ACUSON
AcuNav 8F Ultrasound Catheter (for Siemens Systems)
(10135936)**Sep 10, 2024
263 days to decisionK234064 · Product code: **OWQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k234064/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Dec 22, 2023
Decision date	Sep 10, 2024
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Medline ReNewal Reprocessed Siemens ACUSON AcuNav 8F Ultrasound Catheter (for GE Systems) (10135910)

APPLICANT

Company	Surgical Instrument Service and Savings, Inc.
Location	Redmond, OR, US
Contact	Stephanie Boyle Mays
510(k) history	23 submissions · 23 cleared · 2016-2025

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