

K072051 NOVATOME, MODEL: SU101-50Oct 3, 2007
69 days to decisionK072051 · Product code: **DWZ** · CardiovascularSource: <https://www.510kdatabase.net/k072051/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Biopsy, Endomyocardial (DWZ)
Date received	Jul 26, 2007
Decision date	Oct 3, 2007
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Scholten Surgical Instruments, Inc.
Location	Redwood City, CA, US
Contact	JIM VAN ANDEL
510(k) history	8 submissions · 8 cleared · 1985-2007

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