

K161234 CASSI II Rotational Core Biopsy SystemAug 3, 2016
93 days to decisionK161234 · Product code: **KNW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k161234/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Biopsy (KNW)
Date received	May 2, 2016
Decision date	Aug 3, 2016
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Scion Medical Technologies, LLC
Location	Sauk Centre, MN, US
Contact	Louis Li
510(k) history	6 submissions · 6 cleared · 2013-2017

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