

K152596 Intact® Gen2 SystemFeb 15, 2016
158 days to decisionK152596 · Product code: **KNW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k152596/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Sep 10, 2015
Decision date	Feb 15, 2016
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Intact Medical Corporation
Location	Natick, MA, US
Contact	JOHN VACHA
510(k) history	4 submissions · 4 cleared · 2006-2016

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