

K173316 SpeedBird Model SB38 Soft Tissue Biopsy DeviceJun 19, 2018
243 days to decisionK173316 · Product code: **KNW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k173316/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Oct 19, 2017
Decision date	Jun 19, 2018
Days to decision	243 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	SpeedBird Model SBU Soft Tissue Biopsy Device; SpeedBird Model SBU99 Soft Tissue Biopsy Device

APPLICANT

Company	Transmed7, LLC
Location	Portola Valley, CA, US
Contact	James Vetter
510(k) history	2 submissions · 2 cleared · 2018-2020

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