

**K201244 Concorde Models Concorde US and Concorde ST Soft Tissue Biopsy Devices**Aug 7, 2020  
91 days to decisionK201244 · Product code: **KNW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k201244/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Biopsy (KNW)
Date received	May 8, 2020
Decision date	Aug 7, 2020
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201244/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026