K201244 Concorde Models Concorde US and Concorde ST Soft Tissue Biopsy Devices

CLEARED

Aug 7, 2020
91 days to decision

K201244 · 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	**Transmed7, LLC**
Location	Portola Valley, CA, US
Contact	James Vetter
510(k) history	2 submissions · 2 cleared · 2018-2020