FDA 510(k) Premarket Notification

K212830 CT3000Pro

CLEARED

Dec 21, 2021
105 days to decision

K212830 · Product code: **FEN** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k212830/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Cystometric, Hydraulic (FEN)
Date received	Sep 7, 2021
Decision date	Dec 21, 2021
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Srs Medical**
Location	North Billerica, MA, US
Contact	Lee Brody
510(k) history	1 submissions · 1 cleared · 2021-2021