

K212830 CT3000ProDec 21, 2021
105 days to decisionK212830 · Product code: **FEN** · Gastroenterology & UrologySource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212830/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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