

K223249 Pro-Tx Endorectal Balloon (PROT-25)Feb 10, 2023
151 days to decisionK223249 · Product code: **PCT** · Radiology
Source: <https://www.510kdatabase.net/k223249/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Prostate Immobilizer Rectal Balloon (PCT)
Date received	Sep 12, 2022
Decision date	Feb 10, 2023
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dtx Medical, Inc.
Location	Pittsburgh, PA, US
Contact	Paul Lawson
510(k) history	2 submissions · 2 cleared · 2023-2025

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