

K243057 TrueFit BolusOct 23, 2024
26 days to decisionK243057 · Product code: **MUJ** · Radiology
Source: <https://www.510kdatabase.net/k243057/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Sep 27, 2024
Decision date	Oct 23, 2024
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	TrueFlex Bolus

APPLICANT

Company	Adaptiiv Medical Technologies, Inc.
Location	Halifax, CA
Contact	Olga Zhuk
510(k) history	3 submissions · 3 cleared · 2024-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243057/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026