FDA 510(k) Premarket Notification

K260308 TrueFit Bolus

CLEARED

Feb 19, 2026
20 days to decision

K260308 · Product code: **MUJ** · Radiology
Source: https://www.510kdatabase.net/k260308/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Jan 30, 2026
Decision date	Feb 19, 2026
Days to decision	20 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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