

K253942 Pulmonex II Xenon System (132-503)

Jul 7, 2026
210 days to decision

K253942 · Product code: IYT · Radiology
Source: <https://www.510kdatabase.net/k253942/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Rebreathing, Radionuclide (IYT)
Date received	Dec 9, 2025
Decision date	Jul 7, 2026
Days to decision	210 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Mirion Technologies (Capintec), Inc.
Location	Florham Park, NJ, US
Contact	Mary Anne Yusko
510(k) history	1 submissions · 1 cleared · 2026-2026