

K254180 PerfusiX-Imaging

Jul 24, 2026
213 days to decision

K254180 · Product code: **OWN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k254180/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	Dec 23, 2025
Decision date	Jul 24, 2026
Days to decision	213 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	LIMIS Development B.V.
Location	Leeuwarden, NL
Contact	Kelsey van Abbema
510(k) history	1 submissions · 1 cleared · 2026-2026