

K250655 Deep Capsule® (Deep Capsule US)Mar 12, 2026
372 days to decisionK250655 · Product code: **QZF** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k250655/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Capsule Endoscopy Analysis Software Device (QZF)
Date received	Mar 5, 2025
Decision date	Mar 12, 2026
Days to decision	372 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Digestaid - Artificial Intelligence Development SA
Location	Gondomar, PT
Contact	Miguel Mascarenhas
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250655/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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