

K251286 Affirm 400Jan 21, 2026
271 days to decisionK251286 · Product code: **QFX** · Neurology
Source: <https://www.510kdatabase.net/k251286/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diagnostic Neurosurgical Microscope Filter (QFX)
Date received	Apr 25, 2025
Decision date	Jan 21, 2026
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Digital Surgery Systems, Inc. (D.B.A True Digital Surgery)
Location	Goleta, CA, US
Contact	Lu Ju
510(k) history	2 submissions · 2 cleared · 2025-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251286/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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