

**K252226 Dual Lumen Extended Length Catheter (dELC), 6F,
12cm (320101)**Aug 13, 2025
28 days to decisionK252226 · Product code: **NQJ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k252226/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Hemodialysis, Non-implanted, Ultrafiltration, For Peripheral Use (NQJ)
Date received	Jul 16, 2025
Decision date	Aug 13, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Dual Lumen Extended Length Catheter (dELC), 6F, 16 cm (320102)

APPLICANT

Company	Nuwellis, Inc.
Location	Eden Prairie, MN, US
Contact	Neil Ayotte
510(k) history	2 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Avio Medtech Consulting
Contact	Sydney Wiggins

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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