

K233515 Dual Lumen Extended Length Catheter (dELC), 6F, 12 cm (320101), Dual Lumen Extended Length Catheter (dELC), 6F, 16 cm (320102)

Dec 26, 2023
55 days to decision

K233515 · Product code: **NQJ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k233515/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Non-implanted, Ultrafiltration, For Peripheral Use (NQJ)
Date received	Nov 1, 2023
Decision date	Dec 26, 2023
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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