FDA 510(k) Premarket Notification

K252213 Bendit17 Microcatheter

CLEARED

Dec 3, 2025
141 days to decision

K252213 · Product code: **QJP** · Neurology
Source: https://www.510kdatabase.net/k252213/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Jul 15, 2025
Decision date	Dec 3, 2025
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bend IT Technologies, Ltd.**
Location	Petach Tikva, IL
Contact	Simona Beilin Nissan
510(k) history	4 submissions · 4 cleared · 2019-2025

REGULATORY CONSULTANT

Consulting firm	**Heyer Regulatory Solutions**
Contact	Sheila Hemeon-Heyer

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k252213/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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