

K203842 Bendit21 MicrocatheterApr 13, 2022
468 days to decisionK203842 · Product code: **QJP** · Neurology
Source: <https://www.510kdatabase.net/k203842/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Percutaneous, Neurovasculature (QJP) |
| Date received | Dec 31, 2020 |
| Decision date | Apr 13, 2022 |
| Days to decision | 468 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, LLC |
| Contact | Sheila Hemeon-Heyer |

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

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