

K192998 Reprocessed BRK Transseptal NeedleJul 22, 2020
268 days to decisionK192998 · Product code: **NMK** · CardiovascularSource: <https://www.510kdatabase.net/k192998/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Trocar, Reprocessed (NMK) |
| Date received | Oct 28, 2019 |
| Decision date | Jul 22, 2020 |
| Days to decision | 268 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Innovative Health, LLC |
| Location | Scottsdale, AZ, US |
| Contact | Amanda Babcock |
| 510(k) history | 48 submissions · 48 cleared · 2016-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192998/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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