

K203592 Tigertriever and Tigertriever 17 Revascularization Device

Mar 23, 2021
105 days to decision

K203592 · Product code: **NRY** · Neurology
Source: <https://www.510kdatabase.net/k203592/>

SUBMISSION DETAILS

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Thrombus Retriever (NRY) |
| Date received | Dec 8, 2020 |
| Decision date | Mar 23, 2021 |
| Days to decision | 105 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Rapid Medical , Ltd. |
| Location | Yokneam, IL |
| Contact | Orit Yaniv |
| 510(k) history | 9 submissions · 7 cleared · 2019-2026 |

REGULATORY CONSULTANT

| | |
|-----------------|-----------------------------|
| Consulting firm | Hogan Lovells US LLP |
| Contact | Janice Hogan |

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

CLINICAL EVIDENCE - NCT03474549

Treatment With Intent to Generate Endovascular Reperfusion

| | |
|-------------------|--------------------------|
| Status | Completed |
| Enrollment | 160 patients (actual) |
| Study sites | 17 sites |
| Condition studied | Ischemic Stroke |
| Primary purpose | Treatment |
| Study type | Interventional |
| Study design | Single group |
| Masking | Open label |
| Completion date | Jun 30, 2020 |
| Sponsor | Rapid Medical (Industry) |

Primary outcome

Successful Reperfusion, Defined as mTICI Score ? 2b

Secondary outcome

Modified Rankin Scale (mRS) Score of ?2

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03474549