

K211307 GalaSTITCH Absorbable Monofilament SutureMay 27, 2021
28 days to decisionK211307 · Product code: **NWJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211307/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Suture, Recombinant Technology (NWJ) |
| Date received | Apr 29, 2021 |
| Decision date | May 27, 2021 |
| Days to decision | 28 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Tepha, Inc. |
| Location | Cambridge, MA, US |
| Contact | Jodie Giordano |
| 510(k) history | 18 submissions · 17 cleared · 2007-2024 |

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