

K153089 "Cottony" II TAPE, PLEDGETSAug 12, 2016
291 days to decisionK153089 · Product code: **GAT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k153089/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Suture, Nonabsorbable, Synthetic, Polyethylene (GAT) |
| Date received | Oct 26, 2015 |
| Decision date | Aug 12, 2016 |
| Days to decision | 291 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Teleflexmedical, Inc. |
| Location | Jeffrey, NH, US |
| Contact | Natalie Hichak |
| 510(k) history | 64 submissions · 61 cleared · 1985-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153089/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 2, 2026