

**K130326 TEPHAFLEX MELTBLOWN CONSTRUCT**May 7, 2013  
88 days to decisionK130326 · Product code: **OOD** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k130326/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Surgical Film (OOD)                |
| Date received         | Feb 8, 2013                        |
| Decision date         | May 7, 2013                        |
| Days to decision      | 88 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Tepha, Inc.</b>                      |
| Location       | Cambridge, MA, US                       |
| Contact        | MARY P LEGRAW                           |
| 510(k) history | 18 submissions · 17 cleared · 2007-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130326/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026