

**K973462 SOFTFORM FACIAL IMPLANT**Nov 24, 1997  
73 days to decisionK973462 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k973462/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Mesh, Surgical, Polymeric (FTL)    |
| Date received         | Sep 12, 1997                       |
| Decision date         | Nov 24, 1997                       |
| Days to decision      | 73 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Tissue Technologies, Inc.</b>      |
| Location       | Albuquerque, NM, US                   |
| Contact        | JESSE KRAMER, PH.D                    |
| 510(k) history | 9 submissions · 9 cleared · 1995-2000 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973462/> 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 July 3, 2026