

**K970702 SPECTRUM DESIGNS SPECTRAGEL**May 12, 1997  
75 days to decisionK970702 · Product code: **MDA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k970702/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Traditional                                    |
| Device classification | Elastomer, Silicone, For Scar Management (MDA) |
| Date received         | Feb 26, 1997                                   |
| Decision date         | May 12, 1997                                   |
| Days to decision      | 75 days  |
| Third-party review    | No   |
| Summary / Statement   | Statement                                      |

**APPLICANT**

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|----------------|---|
| Company        | <b>Spectrum Designs, Inc.</b>           |
| Location       | Goleta, CA, US                          |
| Contact        | JIM DISHMAN                             |
| 510(k) history | 18 submissions · 18 cleared · 1994-1999 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970702/> 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 4, 2026