

K970361 LASER EYE GOGGLESMar 18, 1997
46 days to decisionK970361 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k970361/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Jan 31, 1997 |
| Decision date | Mar 18, 1997 |
| Days to decision | 46 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Stefanovsky & Assoc. |
| Location | Walker, MI, US |
| Contact | DAVID W STEFANOVSKY |
| 510(k) history | 3 submissions · 3 cleared · 1983-1997 |

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