

K943117 INTRA-SONIX UROFIBERAug 4, 1994
38 days to decisionK943117 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k943117/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Laparoscope, General & Plastic Surgery (GCJ) |
| Date received | Jun 27, 1994 |
| Decision date | Aug 4, 1994 |
| Days to decision | 38 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Intra-Sonix, Inc. |
| Location | Burlington, MA, US |
| Contact | DANIEL MCNULTY |
| 510(k) history | 1 submissions · 1 cleared · 1994-1994 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k943117/> 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 July 6, 2026