

K935538 BAUER TEMNO COAXIAL NEEDLEFeb 22, 1994
98 days to decisionK935538 · Product code: **GDF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k935538/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Guide, Needle, Surgical (GDF) |
| Date received | Nov 16, 1993 |
| Decision date | Feb 22, 1994 |
| Days to decision | 98 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Bauer Medical, Inc. |
| Location | Palm Harbor, FL, US |
| Contact | PATRICK J LAMB |
| 510(k) history | 3 submissions · 3 cleared · 1994-1996 |

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