

K955477 HI-TEC CO2 INSUFFLATOR TYPE 1300Aug 6, 1997
615 days to decisionK955477 · Product code: **HIF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k955477/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Insufflator, Laparoscopic (HIF) |
| Date received | Nov 30, 1995 |
| Decision date | Aug 6, 1997 |
| Days to decision | 615 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Hi Tec Medical Vertriebs-GmbH Fur Innovative Mediz |
| Location | Tuttlingen, DE |
| Contact | ULRICH HENZLER |
| 510(k) history | 2 submissions · 2 cleared · 1995-1997 |

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