

K972057 POWERTREK INSTRUMENTSNov 5, 1997
156 days to decisionK972057 · Product code: **ERL** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k972057/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL) |
| Date received | Jun 2, 1997 |
| Decision date | Nov 5, 1997 |
| Days to decision | 156 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Medtrek Corp. |
| Location | Branford, CT, US |
| Contact | DOM L GATTO |
| 510(k) history | 1 submissions · 1 cleared · 1997-1997 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972057/> 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 5, 2026