

K021811 UNIDRIVE II PLUS DISPOSABLE TUBING SETJun 19, 2002
16 days to decisionK021811 · Product code: **ERL** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k021811/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL) |
| Date received | Jun 3, 2002 |
| Decision date | Jun 19, 2002 |
| Days to decision | 16 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Mtp Medical Technical Promotion GmbH |
| Location | Culver City, CA, US |
| Contact | JAMES A LEE |
| 510(k) history | 10 submissions · 10 cleared · 1999-2009 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k021811/> 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 May 21, 2026