

K020581 COLOSHIELD COLONOSCOPY DRAPE MODEL E2000Sep 18, 2002
209 days to decisionK020581 · Product code: **KKX** · General Hospital
Source: <https://www.510kdatabase.net/k020581/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Drape, Surgical (KKX) |
| Date received | Feb 21, 2002 |
| Decision date | Sep 18, 2002 |
| Days to decision | 209 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Medical Concepts Development, Inc. |
| Location | St. Paul, MN, US |
| Contact | ERIC EUTENEUER |
| 510(k) history | 6 submissions · 5 cleared · 1986-2002 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k020581/> 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 2, 2026