

K881083 GENERAL PURPOSE KITApr 7, 1988
24 days to decisionK881083 · Product code: **LRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k881083/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------|
| Decision | Substantially Equivalent - SD |
| Submission type | Traditional |
| Device classification | General Surgery Tray (LRO) |
| Date received | Mar 14, 1988 |
| Decision date | Apr 7, 1988 |
| Days to decision | 24 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Med-Dex Intl. |
| Location | Irvine, CA, US |
| Contact | DIANE MOMODA-MADISON |
| 510(k) history | 4 submissions · 3 cleared · 1988-1989 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k881083/> 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 7, 2026