

K881163 RECTANGULAR NITINOL ARCH WIREApr 7, 1988
20 days to decisionK881163 · Product code: **EJF** · DentalSource: <https://www.510kdatabase.net/k881163/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Bracket, Metal, Orthodontic (EJF) |
| Date received | Mar 18, 1988 |
| Decision date | Apr 7, 1988 |
| Days to decision | 20 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Flexmedics |
| Location | Minneapolis, MN, US |
| Contact | SIEVERT, JR. |
| 510(k) history | 20 submissions · 20 cleared · 1986-1999 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k881163/>; 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 22, 2026