

K790125 ULNAR HEAD PROTHESISFeb 8, 1979
16 days to decisionK790125 · Product code: **KXE** · Orthopedic
Source: <https://www.510kdatabase.net/k790125/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Wrist, Hemi-, Ulnar (KXE) |
| Date received | Jan 23, 1979 |
| Decision date | Feb 8, 1979 |
| Days to decision | 16 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Cutter Laboratories, Inc. |
| Location | Mchenry, IL, US |
| Website | https://www.bayer.com |
| 510(k) history | 39 submissions · 39 cleared · 1976-1986 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k790125/>; 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