FDA 510(k) Premarket Notification

K790125 ULNAR HEAD PROTHESIS

CLEARED

Feb 8, 1979
16 days to decision

K790125 · 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