FDA 510(k) Premarket Notification

K802319 HEMOTEMP TM

CLEARED

Oct 10, 1980
17 days to decision

K802319 · Product code: **KSE** · Hematology
Source: https://www.510kdatabase.net/k802319/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Refrigerator, Freezer, Blood Storage (KSE)
Date received	Sep 23, 1980
Decision date	Oct 10, 1980
Days to decision	17 days
Third-party review	No

APPLICANT

Company	**Marion Laboratories, Inc.**
Location	Mchenry, IL, US
510(k) history	38 submissions · 34 cleared · 1978-1989

Marion Laboratories, Inc. was a U.S. pharmaceutical company based in Kansas City, Missouri, specializing in bringing to market drugs discovered but unmarketed by other companies. The company operated from 1950 until 1996. Marion Laboratories received FDA 510(k) clearances from total submissions between 1978 and 1989. The company's cleared devices span General & Plastic Surgery, Toxicology, and Microbiology categories, reflecting a diverse regulatory portfolio during its active period. This company is now a historical record. No FDA 510(k) clearances have been issued since...