FDA 510(k) Premarket Notification

K831736 TRICYCLIC ANTIDEPRESSANTS

CLEARED

Jul 28, 1983
58 days to decision

K831736 · Product code: **DIF** · Toxicology
Source: https://www.510kdatabase.net/k831736/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	May 31, 1983
Decision date	Jul 28, 1983
Days to decision	58 days
Third-party review	No

APPLICANT

Company	**Utak Laboratories, Inc.**
Location	Mchenry, IL, US
510(k) history	23 submissions · 23 cleared · 1980-1991