FDA 510(k) Premarket Notification

K802278 IN VITRO DIAGNOSTIC STANDARDS

CLEARED

Nov 24, 1980
73 days to decision

K802278 · Product code: **DIF** · Toxicology
Source: https://www.510kdatabase.net/k802278/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Sep 12, 1980
Decision date	Nov 24, 1980
Days to decision	73 days
Third-party review	No

APPLICANT

Company	**Supelco, Inc.**
Location	Mchenry, IL, US
510(k) history	24 submissions · 24 cleared · 1976-1989