FDA 510(k) Premarket Notification

K822197 NEEDLE HOLDERS

CLEARED

Aug 16, 1982
24 days to decision

K822197 · Product code: **LCR** · Toxicology
Source: https://www.510kdatabase.net/k822197/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay, Tobramycin (LCR)
Date received	Jul 23, 1982
Decision date	Aug 16, 1982
Days to decision	24 days
Third-party review	No

APPLICANT

Company	**Kelleher Corp.**
Location	Mchenry, IL, US
510(k) history	94 submissions · 94 cleared · 1982-1983