FDA 510(k) Premarket Notification

K800112 AMBLYOPIA TRAINER

CLEARED

Mar 10, 1980
54 days to decision

K800112 · Product code: **HPL** · Ophthalmic
Source: https://www.510kdatabase.net/k800112/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Fixation, Ac-powered, Ophthalmic (HPL)
Date received	Jan 16, 1980
Decision date	Mar 10, 1980
Days to decision	54 days
Third-party review	No

APPLICANT

Company	**Life-Tech Instruments, Inc.**
Location	Mchenry, IL, US
510(k) history	19 submissions · 19 cleared · 1977-1981