FDA 510(k) Premarket Notification

K821080 HAND KERATOSCOPE

CLEARED

May 24, 1982
35 days to decision

K821080 · Product code: **HLR** · Ophthalmic
Source: https://www.510kdatabase.net/k821080/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Keratoscope, Battery-powered (HLR)
Date received	Apr 19, 1982
Decision date	May 24, 1982
Days to decision	35 days
Third-party review	No

APPLICANT

Company	**Medical Equipment Designs, Inc.**
Location	Mchenry, IL, US
510(k) history	13 submissions · 13 cleared · 1982-1991